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August 26, 2002
Via FEDERAL EXPRESS

Examiner Steven C. Brantley
United States Patent Office
Office of Petitions
2201 South Park Place
Crystal Plaza 4, Suite 3C23
Arlington, Virginia 22202

Re: **U.S. Patent Application for
THERMAL BLANKET**
Serial No.: 08/419,719 - Filed April 10, 1995
Our Docket no.: AUGA01000010
Client No.: 103806-153959

Dear Examiner Brantley:

I enclose a copy of the file history of the referenced patent application for use by the United States Patent Office in reconstructing the file. If you have any questions, or if anything further is required, please contact me via telephone at 1-858-638-6747.

Thank you very much for your kind and helpful assistance in this matter.

Gray Cary Ware & Freidenrich LLP

By: Terrance A. Meador

Terrance A. Meador

Reg. # 30,298

tmeador@graycary.com

TAM:rc

Enclosure

Cc: John P. Rock, Augustine Medical, Inc. (w/out enclosure)

Gray Cary\GT\6292272.1
103806-153959

GRAYCARY. TECHNOLOGY'S LEGAL EDGE®

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FAX TRANSMISSION COVER SHEET

December 4, 2001

To:

Telephone:

Fax Number:

Examiner S. Brantley
USPTO

703-308-6916

From: Terrance A. Meador
858-638-6747

Client-Matter Number: AUGA01000010

Re: Petition to Revive

U.S. Patent Application No. 08/419,719 filed 4/10/95

Pages: - 21 - (including this form) Originals: ☐ will be mailed ☐ will not be mailed

If there is a problem with this transmission, please call (858) 667-1498

Fax Operator/Ext. Marcia

Message:

Please find following a Petition and the associated documents for the above-referenced application.

- Petition dated 12/4/01
- Notice of Withdrawal from Issue (Paper No. 19), mailed 6/2/97
- Transmittal & Communication responsive to Paper No. 19, mailed 3/1/99
- Transmittal, Communication, Change of Address, IDS/1449, all dated 7/22/99
- Status Inquiry dated 9/11/00
- Three (3) USTPO stamped postcards
- Copy of Docket record

CONFIDENTIALITY NOTICE

This communication is ONLY for the person named above. Unless otherwise indicated, it contains information that is confidential, privileged or exempt from disclosure under applicable law. If you are not the person named above, or responsible for delivering it to that person, be aware that disclosure, copying, distribution or use of this communication is strictly PROHIBITED. If you have received it in error, or are uncertain as to its proper handling, please immediately notify us by collect telephone and mail the original to us at the above address. Thank you.

(Form Rev. 6/5/00)

Docket No.:AUGA01000010
Serial No.: 08/419,719
Filed: 04/10/95

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
)
Scott D. Augustine et al.) Group No. 3904
)
Serial No.: 08/419,719) Examiner: M. Graham
)
Filed: 04/10/95) Docket No.: AUGA01000010
)
For: THERMAL BLANKET

CERTIFICATION UNDER 37 CFR § 1.8	
I hereby certify that this correspondence is being submitted via facsimile to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this date: <u>4 December 2001</u>	
Date <u>4 December 2001</u>	Signature <u>Tennant A. M. [Signature]</u>

**Attention: Office of Petitions
BOX DAC
Assistant Commissioner for Patents
Washington, D.C. 20231**

ATTN: Examiner S. Brantley

**PETITION UNDER 37 CFR 1.183 FOR REVIVAL OF AN ABANDONED PATENT
APPLICATION AND RECONSTRUCTION OF A MISSING FILE**

The above-identified application became abandoned due to a failure by the United States Patent and Trademark Office to notify the applicant of action to be taken (if any).

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

This application was allowed by a notice of Allowance dated 02/03/97. The Issue Fee was paid by a transmittal mailed on 03/04/97. A Communication mailed on 10/21/97 informed the examiner of the entry of judgement on 09/26/97 in Augustine Medical, Inc., v. Gaymar Industries and in Augustine Medical, Inc. v. Mallinckrodt Medical, Inc. ("the litigation"). Augustine Medical, Inc. is the assignee of this application. On 11/17/97, an Information Disclosure Statement was submitted to disclose the merger of reexamination and reissue proceedings in US Patent No.

Docket No.:AUGA01000010
Serial No.: 08/419,719
Filed: 04/10/95

5,405,371. On 06/02/97, the Office mailed Paper # 19 in this application giving notice that the application was being withdrawn from issue to reopen prosecution. A copy of that notice is enclosed. No further communication respecting the reopening of prosecution has ever been received by the applicant.

On 03/01/99, the applicant mailed a Communication requesting notice of the status of this application, noting that a filing receipt in a related application (08/859,891) indicated that this application had been abandoned. A copy of that Communication is enclosed, together with a copy of a stamped postcard showing receipt of the Communication by the Office. Except for the postcard, no response from the Office to the Communication of 03/01/99 was ever received.

On 07/22/99, the applicant submitted a Communication in this application that forwarded an Information Disclosure Statement to disclose an update in the status of the litigation. A copy of the Communication is enclosed, together with a copy of a stamped postcard showing receipt of the Statement by the Office. Except for the postcard, no response from the Office to the Communication of 07/22/99 was ever received.

The applicant submitted a Status Inquiry on 09/11/00 requesting the Office to notify the applicant of the status of this application. A copy of the Status Inquiry is enclosed, together with a copy of a stamped postcard showing receipt of the Status Inquiry by the Office. Except for the postcard, no response from the Office to the Status Inquiry of 09/11/00 was ever received.

On or about 11/12/01, the undersigned held a telephonic interview with Examiner M. Graham regarding the status of this application and seeking direction as to a course of action. The examiner, who was most helpful, consulted the Office's internal application status database and informed the undersigned that the database indicated the application was in indeed an abandoned status and that the record further indicated the file had been lost.

With the exception of the return postcards already mentioned, no paper mailed by the Office

Gray Cary\GT\6266546.1
103806-153959

Docket No.:AUGA01000010
Serial No.: 08/419,719
Filed: 04/10/95

(including a Notice of Abandonment) has been received in this application following the notice of withdrawal from issue. A copy of the docket record for this application is submitted in this regard.

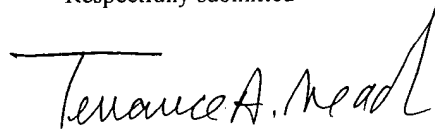
In view of the lack of correspondence from the Office, the applicant has been unable to prosecute this application. If the application is, indeed, abandoned, the abandonment was both unavoidable and unintentional. However, the applicant cannot fulfill the conditions set forth in 37 CFR 1.137 for revival in either case, having no outstanding Office Action or Notice to respond to. Accordingly, in the interest of doing justice in this case, the applicant respectfully requests that the Commissioner suspend the rules, revive the application, inform the applicant of the revival and issue an appropriate paper.

APPLICANT HEREBY PETITIONS FOR RECONSTRUCTION OF THIS FILE

If the file is lost and cannot be recovered or otherwise found, the applicant will make all file materials in its possession that are relevant to this application available for reconstruction of the file. In this regard, the applicant also petitions for reconstruction of the file.

If any fee is required, the Office is authorized to charge the fee to Deposit Account 07-1895 in the name of Gray Cary Ware & Freidenrich. In the event that the Commissioner determines that a fee is necessary, the undersigned respectfully requests notice of such.

Respectfully submitted



TERRANCE A. MEADOR
Reg. No. 30, 298

Date: 4 December 2001

GRAY CARY WARE & FREIDENRICH
4365 Executive Drive, Suite 1100
San Diego, CA 92121-2133

Telephone: (858) 638-6747 Fax: (858) 638-6727

RECEIVED

JUN 04 1997

RIP

Baker, Maxham, Jester & Meador



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Paper No.19

TERRANCE A. MEADOR
BAKER, MAXHAM, JESTER & MEADOR
SYMPHONY TOWERS
750 "B" STREET, SUITE 3100
SAN DIEGO, CALIFORNIA 92101

COPY MAILED

JUN 02 1997

**OFFICE OF
PATENT PUBLICATION**

In re Application of
Scott D. Augustine, et al.
Application No. 08/419,719
Filed: April 10, 1995
Attorney Docket No. 1342-119

NOTICE

The purpose of this communication is to inform you that the above - identified application, which has received a patent number or an issue date, is being withdrawn from issue pursuant to 37 CFR 1.313.

The application is being withdrawn for the following purpose: to reopen prosecution. This withdrawal was requested by the Group Director. Any questions concerning this withdrawal should be addressed to the Group Director.

This application is being returned to the Office of the Director of Group 3300.

Telephone inquiries concerning this matter may be directed to the undersigned at (703) 308-5254.

Karna Cooper
Paralegal Specialist
Office of the Director
Office of Patent Publication

DOCKETED

JUN - 4 1997

FILE 842-119 *k*

This USPTO date stamp hereon will acknowledge receipt of:

COMMUNICATION

Applicant: Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: 04/10/95

Enclosures: Transmittal Form; copies of Notice, Request
Form For Filing A Patent Application Under 37
CFR 1.60, Filing Receipt; and one return
postcard.

Mailed:

TAM/jiv
AUGA01000010
103806-153959

1 manhiya

This USPTO date stamp hereon will acknowledge receipt of:

COMMUNICATION

Applicant: Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: 04/10/95

Enclosures: Transmittal Form; copies of Notice, Request
Form For Filing A Patent Application Under 37
CFR 1.60, Filing Receipt; and one return
postcard.

Mailed:

TAM/jiv
AUGA01000010
103806-153959

1 manhiya



use type a plus (+) sign inside this box -



PTO/SB/21 REV 1 (12/97)
Approved for use through 09/30/2000. omb 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	08/419,719	
	Filing Date	04/10/95	
	First Named Inventor	Augustine et al	
	Examiner Name	Graham	
	Group Art Unit	3304	
Total Number of Pages in This Submission	7	Attorney Docket Number	AUGA01000010

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Response <input type="checkbox"/> After Final <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> PTO Form 1449 <input type="checkbox"/> (no.) cited references <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> PTO Form 1533 <input type="checkbox"/> Response to Missing Parts Under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition Checklist and Accompanying Petition <input type="checkbox"/> To Convert a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below): <u>POSTCARD</u> _____ _____
Remarks: COMMUNICATION		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual Name	Terrance A. Meador Reg. No. 30,298 GRAY CARY WARE & FREIDENRICH
Signature	
Date	MARCH 1999

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date: <u>MARCH 1999</u>			
Typed or printed name	Terrance A. Meador		
Signature		Date	MARCH 1999

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
S.D. AUGUSTINE ET AL.)	Group Art Unit: 3304
)	
Serial No.: 08/419,719)	
)	
Filed: April 10, 1995)	Examiner: M. Graham
)	
For: THERMAL BLANKET		

Assistant Commissioner for Patents
Washington, D.C. 20231

ATTN: Mark Graham

Sir:

COMMUNICATION

On June 2, 1997, a Notice (Paper No. 19) was mailed from the Office of Patent Publication to the undersigned. A copy of the paper is attached. The purpose of the Paper was to give notice that the subject patent application was withdrawn from issue by the Office for the purpose of reopening prosecution. The Notice indicated the application was being returned to the Office of the Director of Group 3300. Since the June 2, 1997 Notice, we have received no further communication from the Patent Office regarding this matter.

On May 21, 1997, a Rule 60 Continuation was filed in this application. A copy of the Continuation Request is also attached. The Official Filing Receipt for this Continuation, copy attached, indicated that the subject application, Serial No. 08/419,719 had been abandoned. As evidenced by the Continuation Request, no abandonment was requested.

The undersigned respectfully requests information as to the status of this application
and the location of its file.

Respectfully submitted,

Date:

1 March 1999



TERRANCE A. MEADOR
Reg. No. 30,298

GRAY CARY WARE & FREIDENRICH
401 B Street, Suite 1700
San Diego, California 92101

Telephone (619) 699-2652 Fax (619) 236-1048

The USPTO date stamp hereon will acknowledge receipt of:

SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT

Applicant: Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 09/419,719
Filed: 04/10/95

Enclosures: Transmittal Form; PTO Form 1449; Two (2) cited
references; Change of Address; and one return
postcard; Communication

Mailed: 22 July 1999

TAM/jiv
AUGA01000010
103806-153959

The USPTO date stamp hereon will acknowledge receipt of:

SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT

Applicant: Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 09/419,719
Filed: 04/10/95

Enclosures: Transmittal Form; PTO Form 1449; Two (2) cited
references; Change of Address; and one return
postcard; Communication

Mailed: 22 July 1999

TAM/jiv
AUGA01000010
103806-153959



Use type a plus (+) sign inside this box -



PTO/SB/21 REV 1 (12/97)

Approved for use through 09/30/2000. omb 0651-0032

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of

information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

		Application Number	08/419,719
		Filing Date	04/10/95
		First Named Inventor	Augustine et al
		Examiner Name	Graham
		Group Art Unit	3304
Total Number of Pages in This Submission	5 + Postcard	Attorney Docket Number	AUGA01000010

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Response <input type="checkbox"/> After Final <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> PTO Form 1449 <input checked="" type="checkbox"/> (no.) cited references <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> PTO Form 1533 <input type="checkbox"/> Response to Missing Parts Under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition Checklist and Accompanying Petition <input type="checkbox"/> To Convert a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input checked="" type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input checked="" type="checkbox"/> Communication <input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below): <u>POSTCARD</u>
Remarks:		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual Name	Terrance A. Meador Reg. No. 30,298 GRAY CARY WARE & FREIDENRICH		
Signature			
Date	22 July 1999		

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date: <u>22 July 1999</u>			
Typed or printed name	Terrance A. Meador		
Signature		Date	22 July 1999

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
S.D. AUGUSTINE ET AL.)	Group Art Unit: 3304
)	
Serial No.: 08/419,719)	Examiner: M. Graham
)	
Filed: April 10, 1995)	Docket No.: AUGA01000010
)	
For: THERMAL BLANKET)	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

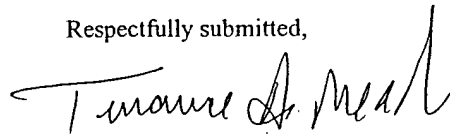
REQUEST FOR CHANGE OF ADDRESS

This is to notify the Office that all correspondence in the subject matter should be addressed to:

TERRANCE A. MEADOR
GRAY CARY WARE & FREIDENRICH
401 B STREET, SUITE 1700
SAN DIEGO, CALIFORNIA 92101

TELEPHONE - (619) 699-2652

Respectfully submitted,



Terrance A. Meador
Reg. No. 30,298

Date: 22 July 1999

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
S.D. AUGUSTINE ET AL.)	Group Art Unit: 3304
)	
Serial No.: 08/419,719)	Examiner: M. Graham
)	
Filed: April 10, 1995)	Docket No.: AUGA01000010
)	
For: THERMAL BLANKET)	

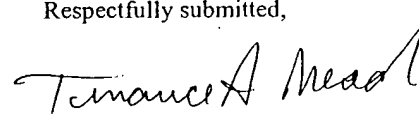
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

COMMUNICATION

Accompanying this paper is an Information Disclosure Statement. On June 2, 1997, a Notice (Paper No. 19) was mailed from the Office of Patent Publication to the undersigned. The purpose of the Paper was to give notice that the subject patent application was withdrawn from issue by the Office for the purpose of reopening prosecution. The litigation related to the subject matter and priority of this application has now been heard on appeal by the Court of Appeals, Federal Circuit. The accompanying Information Disclosure Statement forwards a copy of the Decision on Appeal. Subsequent to the decision, Augustine Medical, Inc., the owner by assignment of this patent application, submitted a Petition For Rehearing And Suggestion For Rehearing In Banc, a copy of which is attached. As of this date, the Federal Circuit has not ruled on the Petition, but has asked that Gaymar and Mallinckrodt respond to the petition.

Respectfully submitted,


TERRANCE A. MEADOR
Registration No. 30,298

Date: 22 July 1999

GRAY CARY WARE & FREIDENRICH
401 B Street, Suite 1700
San Diego, California 92101

Telephone: (619) 699-2652 Fax: (619) 236-1048

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
S.D. AUGUSTINE ET AL.)	Group Art Unit: 3304
Serial No.: 08/419,719)	Examiner: M. Graham
Filed: April 10, 1995)	Docket No.: AUGA01000010
For: THERMAL BLANKET)	

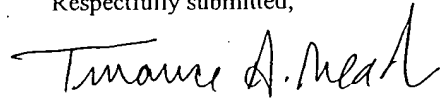
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In satisfaction of their duty of candor and fair dealing, the applicants hereby cite the document listed on the accompanying Form PTO-1449 with respect to the above-identified patent application under the provisions of 37 CFR, 1.97(C) and 1.17(A). The Examiner is respectfully requested to make of record this documents if deemed relevant to the examination of this application.

Respectfully submitted,



TERRANCE A. MEADOR
Registration No. 30,298

Date: 22 July 1999

GRAY CARY WARE & FREIDENRICH
401 B Street, Suite 1700
San Diego, California 92101

Telephone: (619) 699-2652 Fax: (619) 236-1048

perm PTO-1449

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION
(Use Several Sheets If Necessary)

Docket No. AUGA01000010

Application No. 08/419,719

Applicant: Augustine et al

Filing Date: 04/10/95

Group Art Unit 3304

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		US Court of Appeals For The Federal Circuit, DECISION, dated June 8, 1999, <u>Augustine Medical, Inc. vs. Gaymar Industries, Inc. and Medisearch P.R. Inc. and Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc.</u> , 98-1001, -1002, -1054, -1244, -1266, June 8, 1999
		US Court of Appeals For The Federal Circuit, COMBINED PETITION FOR REHEARING AND SUGGESTION FOR REHEARING IN BANC OF PLAINTIFF-CROSS-APPELLANT AUGUSTINE MEDICAL, INC., <u>Augustine Medical, Inc. v. Gaymar Industries, Inc. and Medisearch P.R. Inc. and Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc.</u> , 94-CV-875, 94-CV-888, 96-CV-347 and 96-CV-1145, June 21, 1999

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2/92 PTO)

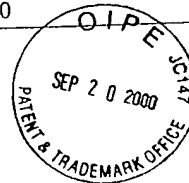
The USPTO date stamp hereon will acknowledge receipt of:

~~CHANGE OF ADDRESS~~ STATUS INQUIRY

Serial No.: 08/419,719

Filed: April 10, 1995

Mailed: September 11, 2000



TAM File No.: AUGA01-10

cmr

The USPTO date stamp hereon will acknowledge receipt of:

~~CHANGE OF ADDRESS~~ STATUS INQUIRY

Serial No.: 08/419,719

Filed: April 10, 1995

Mailed: September 11, 2000

TAM File No.: AUGA01-10

cmr

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)	
Augustine et al)	Group Art Unit: 3904
Serial No.: 08/419,719)	Examiner: Graham
Filed: April 10, 1995)	Atty. Docket: AUGA01000010
For: THERMAL BLANKET)	

BOX: STATUS INQUIRY
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

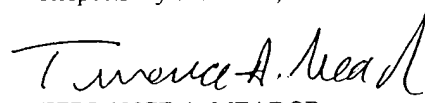
STATUS INQUIRY LETTER

A Notice (Paper No. 19 mailed June 2, 1997) was sent from Ms. Karna Cooper informing that the subject application was being withdrawn from issue. Since that date no Correspondence has been received from the United States Patent and Trademark Office.

The applicants respectfully request the status of this case.

Respectfully submitted,

Date: 11 September 2000


TERRANCE A. MEADOR
Attorney for Applicant
Registration No. 30,298

GRAY CARY WARE & FREIDENRICH
401 B Street, Suite 1700
San Diego, California 92101

Telephone: (619) 699-2652 Fax: (619) 699-3952

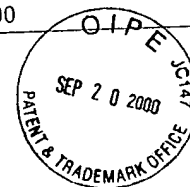
The USPTO date stamp hereon will acknowledge receipt of:

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Serial No.: 08/419,719

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File No.: AUGA01-10

cmr

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)	
Augustine et al)	Group Art Unit: 3904
Serial No.: 08/419,719)	Examiner: Graham
Filed: April 10, 1995)	Atty. Docket: AUGA01000010
For: THERMAL BLANKET)	

BOX: STATUS INQUIRY
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

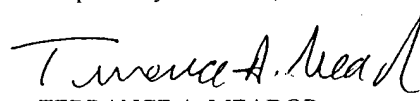
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Respectfully submitted,

Date: 11 September 2000


TERRANCE A. MEADOR
Attorney for Applicant
Registration No. 30,298

GRAY CARY WARE & FREIDENRICH
401 B Street, Suite 1700
San Diego, California 92101

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STATEMENT

Applicant: Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 09/419,719
Filed: 04/10/95

Enclosures: Transmittal Form; PTO Form 1449; Two (2) cited
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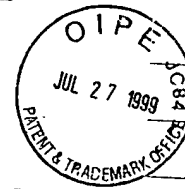
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TRANSMITTAL FORM

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<p>Application Number</p> <p>08/419,719</p>	<p>Filing Date</p> <p>04/10/95</p>
	<p>First Named Inventor</p> <p>Augustine et al</p>
	<p>Examiner Name</p> <p>Graham</p>
	<p>Group Art Unit</p> <p>3304</p>
	<p>Attorney Docket Number</p> <p>AUGA01000010</p>

Total Number of Pages in This Submission 5 + Postcard

ENCLOSURES (check all that apply)

<p><input type="checkbox"/> Fee Transmittal Form</p> <p><input type="checkbox"/> Fee Attached</p> <p><input type="checkbox"/> Amendment/Response</p> <p><input type="checkbox"/> After Final</p> <p><input type="checkbox"/> Extension of Time Request</p> <p><input type="checkbox"/> Express Abandonment Request</p> <p><input checked="" type="checkbox"/> Information Disclosure Statement</p> <p><input checked="" type="checkbox"/> PTO Form 1449</p> <p><input checked="" type="checkbox"/> (no.) cited references</p> <p><input type="checkbox"/> Certified Copy of Priority Document(s)</p> <p><input type="checkbox"/> Response to Missing Parts/Incomplete Application</p> <p><input type="checkbox"/> PTO Form 1533</p> <p><input type="checkbox"/> Response to Missing Parts Under 37 CFR 1.52 or 1.53</p>	<p><input type="checkbox"/> Assignment Papers (for an Application)</p> <p><input type="checkbox"/> Drawing(s)</p> <p><input type="checkbox"/> Licensing-related Papers</p> <p><input type="checkbox"/> Petition Checklist and Accompanying Petition</p> <p><input type="checkbox"/> To Convert a Provisional Application</p> <p><input type="checkbox"/> Power of Attorney, Revocation</p> <p><input checked="" type="checkbox"/> Change of Correspondence Address</p> <p><input type="checkbox"/> Terminal Disclaimer</p>	<p><input type="checkbox"/> After Allowance Communication to Group</p> <p><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences</p> <p><input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)</p> <p><input type="checkbox"/> Proprietary Information</p> <p><input checked="" type="checkbox"/> Communication</p> <p><input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below):</p> <p><u>POSTCARD</u></p>
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<p>Firm or Individual Name</p> <p>Terrance A. Meador Reg. No. 30,298 GRAY CARY WARE & FREIDENRICH</p>	<p>Signature</p> <p><i>Terrance A. Meador</i></p>
<p>Date</p> <p><u>22 July 1999</u></p>	

CERTIFICATE OF MAILING

<p>I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date: <u>22 July 1999</u></p>			
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
S.D. AUGUSTINE ET AL.)	Group Art Unit: 3304
)	
Serial No.: 08/419,719)	Examiner: M. Graham
)	
Filed: April 10, 1995)	Docket No.: AUGA01000010
)	
For: THERMAL BLANKET)	

Assistant Commissioner for Patents
Washington, D.C. 20231

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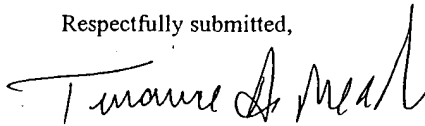
REQUEST FOR CHANGE OF ADDRESS

This is to notify the Office that all correspondence in the subject matter should be addressed to:

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SAN DIEGO, CALIFORNIA 92101

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Respectfully submitted,



Terrance A. Meador
Reg. No. 30,298

Date: 22 July 1999

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
S.D. AUGUSTINE ET AL.)	Group Art Unit: 3304
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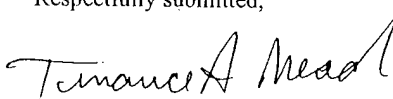
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

COMMUNICATION

Accompanying this paper is an Information Disclosure Statement. On June 2, 1997, a Notice (Paper No. 19) was mailed from the Office of Patent Publication to the undersigned. The purpose of the Paper was to give notice that the subject patent application was withdrawn from issue by the Office for the purpose of reopening prosecution. The litigation related to the subject matter and priority of this application has now been heard on appeal by the Court of Appeals, Federal Circuit. The accompanying Information Disclosure Statement forwards a copy of the Decision on Appeal. Subsequent to the decision, Augustine Medical, Inc., the owner by assignment of this patent application, submitted a Petition For Rehearing And Suggestion For Rehearing In Banc, a copy of which is attached. As of this date, the Federal Circuit has not ruled on the Petition, but has asked that Gaymar and Mallinckrodt respond to the petition.

Respectfully submitted,


TERRANCE A. MEADOR
Registration No. 30,298

Date: 22 July 1999

GRAY CARY WARE & FREIDENRICH
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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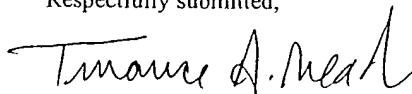
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In satisfaction of their duty of candor and fair dealing, the applicants hereby cite the document listed on the accompanying Form PTO-1449 with respect to the above-identified patent application under the provisions of 37 CFR, 1.97(C) and 1.17(A). The Examiner is respectfully requested to make of record this documents if deemed relevant to the examination of this application.

Respectfully submitted,



TERRANCE A. MEADOR
Registration No. 30,298

Date: 22 July 1999

GRAY CARY WARE & FREIDENRICH
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Telephone: (619) 699-2652 Fax: (619) 236-1048

United States Court of Appeals for the Federal Circuit

98-1001,
-1002, -1054, -1244, -1286

AUGUSTINE MEDICAL, INC.,

Plaintiff-Cross Appellant,

v.

GAYMAR INDUSTRIES, INC.
and MEDISEARCH P R, INC.,

Defendants-Appellants,

and

MALLINCKRODT GROUP, INC.
and MALLINCKRODT MEDICAL, INC.,

Defendants-Appellants.

DECIDED: June 8, 1999

Before MAYER, Chief Judge, RADER, and GAJARSA, Circuit Judges.
RADER, Circuit Judge.

Augustine Medical, Inc. filed two separate lawsuits, one against Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc. (collectively, Mallinckrodt), and another against Gaymar Industries, Inc. and Medisearch P R, Inc. (collectively, Gaymar). Each lawsuit alleged infringement of Augustine Medical's U.S. Patent Nos. 5,300,102 (the '102 patent), 5,324,320 (the '320 patent), 5,405,371 (the '371 patent), 4,572,188 (the '188 patent), and 5,350,417 (the '417 patent) (collectively, the Augustine patents). The Augustine patents claim features of convective (or forced-air) thermal blankets. The

United States District Court for the District of Minnesota consolidated these separate suits for trial. Before trial, the district court granted summary judgment of invalidity of several asserted claims and non-infringement of others. At trial, a jury found infringement of the remaining claims under the doctrine of equivalents. Accordingly, the district court issued a permanent injunction prohibiting Mallinckrodt and Gaymar from making certain convective thermal blankets.

Because prosecution history estoppel limits application of the doctrine of equivalents to the asserted claims, this court reverses the district court's failure to grant judgment as a matter of law (JMOL) of non-infringement and vacates the entry of the permanent injunction. In addition, because the July 10, 1990 parent application does not provide sufficient support for claims 1, 3, 4, and 8 of the '371 patent, this court affirms the district court's decision that those claims are invalid under 35 U.S.C. § 102(b) (1994). This court also affirms the district court's summary judgment of non-infringement on the '188 patent. Finally, this court affirms the dismissal of Gaymar's invalidity claim on the '417 patent.

I.

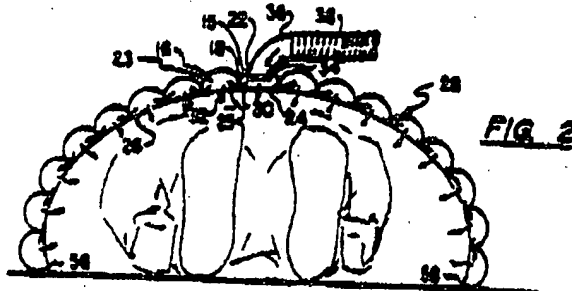
Convective thermal blankets inflate to direct warm (or cool) air onto a person. Surgeons often use these blankets during and after an operation to prevent or treat hypothermia caused by surgical conditions. Hypothermia results when a patient's body temperature drops below a certain threshold. Surgery often presents the threat of hypothermia. A patient's body temperature may drop significantly during surgery because anesthesia prevents the patient's body from regulating its own temperature. Additionally, operating rooms - kept cool to accommodate the surgeon's working

conditions and to reduce the spread of germs -- can chill patients. Moreover, surgery often calls for administration of cool intravenous fluids at a time when the patient's body cavity is open.

A convective thermal blanket over the patient is thus necessary to prevent or treat hypothermia during and after surgery. Heated air from a warming unit inflates the blanket. Once inflated, the blanket directs heated air onto the patient through small holes (or "exit ports") in the undersurface of the blanket. With careful use, a convective blanket regulates patient temperature and prevents hypothermia.

The Augustine patents all stem from related applications and claim features in a particular convective thermal blanket design. Dr. Scott D. Augustine developed these features. The Augustine blanket design contains a series of hollow tubes with rounded upper surfaces and flattened lower surfaces joined in a parallel array. The geometric design of this structure allows it to "self-erect" when inflated and helps the blanket perform its function of warming the patient. According to the earliest of the Augustine patents, the '188 patent, the Augustine blanket has a "self-supporting structure having a generally rounded or elliptical cross-sectional shape which contacts the patient only at the tubes which are immediately adjacent the keystone tube." Col. 4, ll. 12-15. When in use, air pressure from the exit ports raises these tubes slightly above the patient so that none of the tubes are in contact with the patient. This slight gap between the patient and the blanket facilitates "circulation . . . through these exit ports." Col. 4, ll. 16-20. According to the specifications of the other three Augustine patents, the inflated blanket "erects itself into a Quonset hut-like structure." The '102 patent, col. 3, ll. 31-35, 49-50; the '320 patent, col. 3, ll. 11-12, 20-22; the '371 patent, col. 4, ll. 10, 17-19.

Figures in each of the Augustine patents illustrate this self-supporting, Quonset hut-like structure. Figure 2 of the '188 patent is representative.



Mallinckrodt and Gaymar manufacture and sell convective warming blankets to prevent or treat hypothermia. Mallinckrodt's and Gaymar's blankets (the accused blankets) are similar to each other in construction. The accused blankets feature an inflatable quilt-like structure. The accused blankets attach two sheets of the same amount of flexible, lightweight material around their periphery and at various spots along their surfaces. In operation, heated air flows onto a patient's body from holes in the undersurface of the accused blankets, but the blankets do not form a self-supporting or Quonset hut-like structure. Instead, the accused blankets lie flat when inflated on a flat surface and rest substantially on a patient when in use. Mallinckrodt began selling its first model of convective warming blanket in June 1992. Gaymar began selling forced-air blankets in March 1992.

In October 1994, after issuance of the '102 and '320 patents in April and June 1994, Augustine Medical filed separate lawsuits against Mallinckrodt and Gaymar, initially alleging infringement of these two patents only. Augustine Medical later

amended its original complaint to assert infringement of the '371, '188, and '417 patents as well.

After consolidation of these lawsuits in the district court, Mallinckrodt and Gaymar moved for partial summary judgment, seeking a declaration of invalidity as to claims 1, 3, 4, and 8 of the '371 patent. The district court referred the case to a magistrate judge for recommendations. The magistrate judge concluded that the display of a prototype blanket triggered a § 102(b) on-sale bar. In reaching that conclusion, the magistrate judge found that the parent application Serial No. 07/550,757 (the '757 application), which was filed within one year after the display, did not sufficiently describe the invention of these claims of the '371 patent. Thus, the magistrate judge accorded these claims the January 8, 1991 filing date of their continuation-in-part (CIP) application, not the June 10, 1990 filing date of the '757 application. With that finding in place, the magistrate judge recommended granting the summary judgment motion because Augustine Medical had "displayed, sold and distributed a written description of the device" embodying these claims more than one year before the effective filing date of the claims. The district court adopted the magistrate judge's Report and Recommendation and invalidated these claims.

In the fall of 1998, Augustine Medical signed a stipulation of dismissal with prejudice of all infringement claims arising out of the '417 patent. Augustine Medical further stipulated that none of Gaymar's products infringe any claim of the '417 patent. Based on these stipulations, the magistrate judge discerned no actual controversy amongst the parties concerning the '417 patent, thereby mooted Gaymar's claim that the '417 patent was invalid. The district court adopted this conclusion.

Before trial, both Gaymar and Mallinckrodt moved for partial summary judgment of non-infringement of the remaining claims of the '188, '102, '320, and '371 patents. In part, Gaymar and Mallinckrodt based these motions on prosecution history estoppel. With respect to the '188 patent, the district court granted summary judgment of non-infringement in favor of both Mallinckrodt and Gaymar. In this judgment, the district court followed the magistrate judge's recommendation. The magistrate judge had first construed the claims and found, based on that interpretation, that the accused blankets did not literally infringe the '188 patent as a matter of law. Then, based on the "all elements rule," see Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 935, 4 USPQ2d 1737, 1739-40 (Fed. Cir. 1987) (en banc); Wamer-Jenkinson Co. v. Hilton Davis Chemical Co., 50 U.S. 17, ___, 117 S. Ct. 1040, 1054, 41 USPQ2d 1865, 1871 (1997), the magistrate judge stated that application of the doctrine of equivalents to the claims of the '188 patent would render some of the claim elements meaningless. Specifically, because interpreting the claims as advocated by Augustine Medical would eliminate the claim limitations of "flattened," "substantially smooth," and "parallel array of hollow tubes," the district court found that the accused blankets did not infringe the '188 patent under the doctrine of equivalents.

With respect to the other patents, the magistrate judge detected a genuine issue of material fact relative to the "self-erecting" limitation. Specifically, the magistrate judge noted that "the Mallinckrodt blanket move[d] slightly away from the person underneath it and assume[d] a shape over the person" when in operation. When considering the Gaymar blanket, the magistrate judge explained that "the blanket lift[ed] slightly away from the table as it [was] inflated." The magistrate judge also concluded

that two other elements of the Augustine Medical patent claims, a non-inflatable erectable foot drape and a non-inflatable extension at the head end, were present in Gaymar's blankets.

Based on the magistrate judge's Report and Recommendation of July 18, 1997, the district court granted the motions for summary judgment of non-infringement with respect to the '188 patent, but denied the motions with respect to the '102, '320, and '371 patents (the remaining patents in suit). The district court identified the same issue of material fact regarding whether Gaymar's and Mallinckrodt's blankets literally or equivalently self-erect. Neither the magistrate judge nor the district court substantively addressed the prosecution history estoppel defense.

The district court ordered a *seriatim* trial on the remaining patents in suit, with the first phase to determine infringement and willfulness and the second phase to determine damages, if necessary. At trial, the most contested issue between the parties was the meaning of the term "self-erecting." The district court determined that this limitation is either explicitly or implicitly present in each of the disputed patent claims of the '102, '320, and '371 patents. The magistrate judge had defined "self-erecting" to mean that the "blanket forms a structure around the patient when it is inflated." Rather than adopt the magistrate judge's interpretation, however, the district court, in its instructions to the jury, interpreted the term to require "that the device form a curved or arched structure which stands off the patient."

After trial, the jury returned a verdict finding that Mallinckrodt and Gaymar had not literally infringed any of the patent claims, but had infringed all of the asserted claims under the doctrine of equivalents. Based on this verdict, the district court

entered a permanent injunction prohibiting both Gaymar and Mallinckrodt from making, using, or selling certain forced-air warming blankets.

Mallinckrodt and Gaymar both appeal the entry of the permanent injunction. Gaymar and Mallinckrodt also each sought judgment as a matter of law or a new trial under Fed. R. Civ. P. 50(b) and 59. Because these post-trial motions remained pending before the district court at the time of the appeal, the parties appealed under 28 U.S.C. § 1292(a)(1) and (c)(1) (1994). The district court later denied the parties' post-trial motions. Gaymar also appeals the dismissal of its claim of invalidity with respect to the '417 patent. Augustine Medical cross-appeals the grant of summary judgment of invalidity with respect to claims 1, 3, 4, and 8 of the '371 patent and challenges the district court's construction of the "self-erecting" limitation.

II.

Because a correct infringement analysis requires a correct claim interpretation, see Markman v. Westview Instruments, Inc., 52 F.3d 967, 976, 34 USPQ2d 1321, 1328 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996); Key Manufacturing Group, Inc. v. Microdot, Inc., 925 F.2d 1444, 1448, 17 USPQ2d 1806, 1809 (Fed. Cir. 1991); SmithKline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 885, 8 USPQ2d 1468, 1474 (Fed. Cir. 1988), this court begins its review of the jury's verdict with a review of the district court's claim interpretation. This court reviews the district court's claim construction without deference. See Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56, 46 USPQ2d 1169, 1172-75 (Fed. Cir. 1998) (en banc); Markman, 52 F.3d at 979-81.

The primary issue of claim interpretation is the meaning of "self-erecting." Discharging its duty to give meaning to the claims, the district court instructed the jury that the term "self-erecting" required "that the device form a curved or arched structure which stands off the patient." Augustine Medical argues that "self-erecting" requires only that the blanket form an "environment" about the patient in which warm air can circulate. Under its proposed claim interpretation, Augustine Medical argues that the accused blankets literally "self-erect" because they create an environment of circulating warm air about a patient.

This court finds no support for Augustine Medical's claim construction. The patents themselves define what the claims mean by "self-erecting." As noted above, the '188 patent describes its structure as "a self-supporting structure having a generally rounded or elliptical cross-sectional shape which contacts the patient only at the tubes which are immediately adjacent the keystone tube." Col. 4, ll. 12-16. The other patents all explain that a blanket which "self-erects" "erects itself into a Quonset hut-like structure" when inflated. The '102 patent, col. 3, ll. 31-35; the '320 patent, col. 3, ll. 11-12, 20-22; the '371 patent, col. 4, ll. 10, 17-19. Thus, the district court correctly construed the term "self-erecting" to require that the accused blankets "form a curved or arched structure which stands off the patient." Following this interpretation, the jury found that the accused blankets did not literally infringe. The jury did, however, find infringement under the doctrine of equivalents.

As noted earlier, the accused blankets are made of a flexible, lightweight material which rests substantially on a patient when in use. When inflated, air exits through ports in the bottom of the blanket and passes over the patient's body. The

evidence suggests that the accused blankets raise slightly away from the patient's body in the areas adjacent to the exit ports. The magistrate judge noted that "while viewing the inflation of the Mallinckrodt device in court and on video, . . . the Mallinckrodt blanket move[d] slightly away from the person underneath it and assume[d] a shape over the person." When considering the Gaymar blanket, the magistrate judge explained that "the blanket lift[ed] slightly away from the table as it [was] inflated." Because the accused blankets assume the contours of, and rise slightly above, the patient's body, Augustine Medical contends that there is substantial evidence to support the jury's finding that the accused blankets at least contain an equivalent to the claimed "self-erecting" limitation.

In reviewing challenges to the sufficiency of the evidence supporting a jury verdict of infringement under the doctrine of equivalents, this court determines whether substantial evidence supports the jury's findings. See Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567, 39 USPQ2d 1492, 1499 (Fed. Cir. 1996). Although the doctrine of equivalents may occasionally extend the reach of a claim beyond its literal scope, several principles strictly limit application of the doctrine. For instance, the "all elements" rule provides the analytical framework for conducting an infringement analysis under the doctrine of equivalents that avoids undue expansion of a patent's claims. See Litton Sys., Inc. v. Honeywell, Inc., 140 F.3d 1449, 1464, 48 USPQ2d 1321, 1324 (Fed. Cir. 1998). Prosecution history estoppel also limits undue expansion of a claim's scope through the doctrine of equivalents. See Warner-Jenkinson, 117 S. Ct. at 1047, 1049-51. Specifically, prosecution history estoppel prevents a patentee from recapturing subject matter surrendered during prosecution of

the patent. See id.; Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579-81, 34 USPQ2d 1673, 1679 (Fed. Cir. 1995). The application of prosecution history estoppel is a question of law which this court decides without deference to the district court. See Cybor, 138 F.3d at 1460.

To determine the scope of estoppel, this court examines objectively whether a competitor would reasonably conclude that an applicant's prosecution conduct had surrendered the disputed subject matter. See Cybor, 138 F.3d at 1457 ("The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter."). "Either amendments or arguments made by an applicant may be the basis for this conclusion." Lifton, 140 F.3d at 1462.

Although not dispositive, the prior art may aid in determining the scope of an estoppel. "[A] patentee is estopped from recovering through equivalency that which was deemed unpatentable in view of the prior art." Pali Corp. v. Micron Separations, Inc., 86 F.3d 1211, 1219, 38 USPQ2d 1225, 1230 (Fed. Cir. 1995). After adding a claim limitation during prosecution to overcome prior art, the applicant cannot later assert that the distinguished feature of the prior art is equivalent to the added limitation. See Lifton, 140 F.3d at 1462. Similarly, the patentee may not assert coverage of a "trivial" variation of the distinguished prior art feature as an equivalent. See id. "if sufficient to evince a clear and unmistakable surrender of subject matter," arguments made during prosecution "may [also] estop an applicant from recapturing that surrendered matter under the doctrine of equivalents." Id. at 1468. This court, therefore, must consider whether the prosecution history of the Augustine patents

precludes Augustine Medical from asserting coverage of the accused blankets under the doctrine of equivalents.

The specifications and file histories of the Augustine patents contain clear representations that not only define the scope of the "self-erecting" limitation, but also show that the claims cover only convective warming blankets which are "self-erecting." The specification of the '188 patent references two primary categories of prior art thermal blankets, conductive and convective. The '188 patent criticizes conductive prior art blankets because they touch the patient. The '188 patent explains that conductive blankets provide little warmth beyond the areas in direct contact with the blanket. Col. 1, ll. 23-30. Outside these local areas of warmth in direct contact with the blanket, conductive blankets transfer only minimal warmth by heat radiation. Col. 1, ll. 33-36. This combination of conductive and radiative heating results in non-uniform heat transfer. The parts of the patient's body in direct contact with the blanket have a significantly higher temperature than the average body temperature while the other parts of the patient's body have a significantly lower temperature. Col. 1, ll. 25-30. Additionally, the '188 specification explains, conductive blankets carry a significant risk of burning the patient's skin at points of direct contact. Col. 1, ll. 30-33.

The '188 patent also criticizes convective prior art blankets. In these blankets, as in the '188 claimed invention itself, a heat transfer medium such as air circulates to provide temperature control. Col. 1, ll. 37-47. Convective thermal blankets are not new. The convective prior art referenced in the '188 patent includes U.S. Patent No. 2,093,834 (Gaugler) which issued in 1937. In fact, Mallinckrodt and Gaymar both claim to have based their blanket design on expired U.S. Patent No. 2,512,559 (Williams).

U.S. Patent Nos. 2,110,022 (Kliesrath) and 4,660,388 (Greene) also disclose certain convective thermal blankets.

The '188 patent specifically discusses the disadvantages of the Kliesrath convective cover. According to the '188 patent, the Kliesrath convective blanket circulates air "inside a flexible bag which has a top insulating layer and a bottom heat conducting layer which contacts the patient." Col. 1, ll. 39-42. According to Kliesrath, the "heat conducting layer" is "a relatively thin sheet of cotton, linen, silk or the like," that allows passage of warm air to transfer heat onto the patient. Kliesrath, col. 2, ll. 4-5, 21-27; col. 1, ll. 31-35. The '188 patent criticizes the structure of the Kliesrath blanket as "unnecessarily heavy and rigid." Col. 1, ll. 42-43. Specifically, the '188 patent complains that "the weight of the blanket can press its inner surface against the covered patient and block a number of the exit ports, thereby reducing the total body area over which the air is circulated." Col. 1, ll. 43-47.

As a solution to the problems of both the conductive and convective prior art blankets, the '188 patent introduces "a lightweight, flexible, inflatable casing [which inflates] into a self-supporting structure which encloses the patient." Col. 1, ll. 55-56. The specification of the '188 patent thereby invokes its self-erecting structure to distinguish the invention from both convective and conductive prior art thermal blankets. Col. 1, ll. 63-66; col. 2, ll. 12-18.

The '102 patent, dated April 1994, incorporated the description of the prior art in the '188 patent by reference. Col. 1, ll. 16-19. The '102 patent additionally describes the invention of the '188 patent as "a self-erecting, inflatable airflow cover." Col. 1, ll. 19-20. The '102 patent proceeds to describe the operation of the '188 claimed

invention: "When inflated, the cover self-erects about a patient, thereby creating an ambient environment about the patient." The '102 patent specification also expressly defines the term "thermal blanket," contained in each of its claims, with reference to the "self-erecting" feature: "the term 'thermal blanket' is meant to invoke a self-erecting, inflatable structure for delivering a thermally controlled inflating medium to the interior of the structure created when the thermal blanket is inflated." Col. 3, ll. 30-34.

After the '102 patent issued, the '320 and '371 patents issued in June 1994 and in April 1996, respectively. Like the '102 patent, the '320 and '371 patents also incorporate the disclosure of the '188 patent by reference and describe the invention as "a self-erecting, inflatable airflow cover." The '320 patent, col. 1, ll. 16-17; the '371 patent, col. 1, ll. 19-20. The Augustine patents therefore identify the "self-erecting" structure as the primary advantage over the prior art. This distinction appears even more prominently in the file histories of the Augustine patents.

The prosecution histories of the Augustine patents show that the applicant expressly surrendered coverage of any forced-air blanket other than a "self-erecting" convective thermal blanket which stands off of a patient when in operation. During prosecution of application No. 07/227,189 (the '189 application), a parent application to later applications resulting in the '102, '320 and '371 patents, Augustine Medical canceled or amended all of the original claims in favor of new claims containing the "self-erecting" limitation. Augustine Medical made these amendments in response to the examiner's rejections over the prior art. The prosecution history explains:

All of the new claims are drawn to a self-erecting, inflatable thermal blanket which bathes a person in a thermally controlled inflating medium. Such a thermal blanket is one which, when inflated, erects about a

person, standing off of the person to exhaust the inflating medium which thereby bathes the person in the medium.

During the prosecution of the '189 application, Augustine Medical also presented arguments to overcome the examiner's reliance on the conductive prior art blanket references. Specifically, Augustine Medical argued:

[T]he airflow cover and the convective thermal blanket, when inflated, stand off a patient. This is vital to the blanket's operation, since contact with the patient would block passage of the inflating medium through the occluded apertures in the undersurface and would prevent the blanket from bathing the patient in an inflating medium.

Because the prosecution history of a parent application may limit the scope of a later application using the same claim term, see Jonsson v. Stanley Works, 903 F.2d 812, 818, 14 USPQ2d 1863, 1870 (Fed. Cir. 1990), these claim amendments and arguments restrict the scope of the claims in each of the later issued patents containing the "self-erecting" limitation.

During prosecution of the application leading to the '102 patent, Augustine Medical again focused on the unique "self-erecting" structure of its blanket to distinguish the Greene and Kliesrath convective prior art. Augustine Medical represented that its "air flow cover consists entirely and solely of an inflatable tubular structure which, when inflated by an inflating medium, erects about a person." According to the applicant, the structure of the claimed invention differs from Greene because it "permits the thermal blanket to assume the shape of a curved surface which curls downwardly toward its edges from its center and forms a quonset-type structure." Still a further reference in the '102 patent file history argues that "the thermal blanket disclosed and claimed in this application is different from the device disclosed by Greene because it self-erects." Augustine Medical therefore clearly asserted that "the

air flow cover of the '188 [patent] and thermal blanket of this application are significantly different from the covers of Greene and Klesrath" because of this self-erecting structure.

Augustine Medical made representations nearly identical to those discussed with reference to the '102 patent to overcome the examiner's reliance on Greene and Klesrath during the prosecution of the application leading to the '371 patent. The prosecution history of the '320 patent also contains limiting representations. Specifically, Augustine Medical distinguished over the prior art by stating that the invention covers the "class of convective thermal blankets, or airflow covers . . . which are inflatable and which self-erect when inflated. When inflated, these blankets cool or warm a patient enclosed in the self-erected structure."

In sum, during prosecution of the '102, '320, and '371 patents, Augustine Medical amended the claims to expressly include a "self-erecting" limitation and made clear representations of the scope of that limitation to overcome the prior art. Augustine Medical therefore surrendered during prosecution the coverage it now seeks to reclaim via the doctrine of equivalents. The record of the administrative proceedings before the PTO precludes coverage of allegedly equivalent blankets which rest on a patient and do not inflate themselves into a self-supporting Quonset hut-like structure. The district court therefore erred by declining to grant Gaymar's and Mallinckrodt's motion for JMOL and by entering a permanent injunction against them. Because this court determines that application of prosecution history estoppel bars Augustine Medical from extending the scope of its patent claims to cover the accused devices, this court need not address

whether Augustine Medical's proof on equivalence was sufficient to support the jury's verdict.

Relying on this court's early statements that pioneering inventions deserve a broader range of equivalents, see, e.g., Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532, 3 USPQ2d 1321, 1323 (Fed. Cir. 1987); Thomas & Betts Corp. v. Litton Sys., Inc., 720 F.2d 1572, 1579, 220 USPQ 1, 6 (Fed. Cir. 1983), Augustine Medical appears to argue that because its patents "revolutionized the treatment of surgical patients" they deserve broader protection. At the outset, this court notes that no objective legal test separates pioneers from non-pioneers. See, e.g., Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d 978, 987, 10 USPQ2d 1338, 1346 (Fed. Cir. 1989) (stating that pioneer status depends on all factual circumstances). Furthermore, it is impossible for this court or the PTO to predict the future of any given technology and thereby determine the likelihood that an invention will open vast new vistas of innovation. The peripheral claiming system itself, however, makes the best distinction between pioneers and non-pioneers. Pioneers enjoy the benefits of their contribution to the art in the form of broader claims. Without extensive prior art to confine and cabin their claims, pioneers acquire broader claims than non-pioneers who must craft narrow claims to evade the strictures of a crowded art field. Thus, claim scope itself generally supplies broader exclusive entitlements to the pioneer. Moreover, a pioneer generally need not fear traditional limits on the application of the doctrine of equivalents such as prior art or prosecution history estoppel (because amendments or arguments to overcome the prior art are generally unnecessary in true pioneer

applications) -- a concept different from Augustine Medical's plea for enhancing the scope of equivalents.

Augustine Medical notes that the extensive convective thermal blanket prior art (with the possible exception of Klesrath which discussed treatment of diseases) did not explain the use of convective warming blankets for the prevention or treatment of hypothermia. To support its claim for a broader scope of equivalents, Augustine Medical points out that before Dr. Augustine's invention in 1988, doctors had used a variety of ineffective methods to treat hypothermia -- such as infra-red heat lamps, hot water mattresses, heat/moisture exchangers, and cotton blankets. Augustine Medical therefore argues that its invention "pioneered" the commercialization of convective warming for the treatment and prevention of hypothermia.

None of Augustine Medical's patents, however, claim a method of preventing and treating hypothermia. Rather, the Augustine patents contain only the apparatus claims discussed above. Even if a court could determine that Dr. Augustine had pioneered a method of treatment, that work cannot expand the coverage of apparatus claims to cover every apparatus used for the same purpose. In sum, although Augustine Medical's apparatus claims give patent protection covering "all uses" for the claimed apparatus, Augustine Medical cannot use the patent laws to proscribe use of another non-infringing apparatus to perform a method which is not claimed.

III.

With respect to Augustine Medical's cross-appeals, this court first addresses the district court's grant of summary judgment of invalidity with respect to claims 1, 3, 4, and 8 of the '371 patent. This court reviews without deference the requirements for

summary judgment. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986). If any genuine issue of material fact remains in dispute, summary judgment is inappropriate. See Fed. R. Civ. P. 58(c). In reviewing a grant of summary judgment, this court resolves all factual inferences and doubts in favor of the non-moving party. See Anderson, 477 U.S. at 266; Chluminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1307, 46 USPQ2d 1752, 1755 (Fed. Cir. 1998).

This court therefore examines the record for genuine factual issues with regard to whether claims 1, 3, 4, and 8 are entitled to the July 1990 priority date of the '371 patent's parent application, the '757 application. If these claims deserve the July 1990 priority date, the display in October 1989 of two prototype blankets occurred after the critical date and could not erect a § 102(b) bar.

The '371 patent issued from an application continued in part from the '757 application. A CIP application contains subject matter from a prior application and may also contain additional matter not disclosed in the prior application. See Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994). Different claims of such an application may therefore receive different effective filing dates. See id. Subject matter that arises for the first time in the CIP application does not receive the benefit of the filing date of the parent application. See id. Thus, the decision on the proper priority date – the parent application date or the CIP application date – for subject matter claimed in a CIP application depends on when that subject matter first appeared in the patent disclosures. To decide this question, a court must examine whether the "disclosure of the application relied upon reasonably convey[s] to the artisan that the inventor had possession at that time of the later claimed subject

matter." Id. (quoting Wang Lab., Inc. v. Toshiba Corp., 993 F.2d 858, 865, 28 USPQ2d 1766, 1774 (Fed. Cir. 1993)). This is a question of fact. See id.

The magistrate judge found that the '757 application does not disclose the subject matter claimed in claims 1, 3, 4, and 8 of the '371 patent. Therefore, the magistrate judge denied these claims the '757 application's July 10, 1990 filing date. These claims each claim a convective warming blanket which covers only a portion of a patient's body. Although Augustine Medical points to passages from the '757 parent application that it asserts supports the claimed subject matter, these passages, in fact, do not at all relate to the claimed subject matter.

With respect to the lower body blanket in claim 1, for example, Augustine Medical refers to statements by its expert witness that language in the specification discussing drawing the blanket "up to the chin area" supports the claimed subject matter. Specifically, Augustine Medical conclusively asserts that this language, in conjunction with the understanding that care sites must be kept visible and clean, supports a blanket covering any other limited body area below the chin, including the lower body blanket of claim 1. To the contrary, this language does not suggest, let alone disclose, a lower body blanket. Rather, the only discussion of care sites relates to those in the head and neck region. Nowhere is there a suggestion, nor is it inherent, that similar blankets may be constructed for the treatment of other care sites.

Similarly, with respect to claims 3, 4, and 8, the passages pointed to as providing support for the claimed subject matter are insufficient. Claim 3 is dependent on claim 1 and is therefore unsupported for the same reasons as claim 1. Claim 4 covers a blanket which is positioned across the arms and chest of a patient's body. Augustine

Medical again points to the statement in the parent application that the blanket could be drawn up to the patient's chin and argues that it is therefore inherent that its blanket "could be positioned in many ways" including transverse disposition of the blanket over a patient's arms and chest. Augustine Medical's conclusory statements are again wholly insufficient to explain how one of skill in the art would find support for the invention in claim 4 from this language of the '757 application. Like claim 4, claim 8 is also directed toward a transverse blanket which covers a patient's arms and chest and is similarly unsupported by the '757 application. For these reasons, no reasonable jury could have found support for claims 1, 3, 4, or 8 of the '371 patent in the '757 application. Accordingly, there is no genuine issue of material fact in dispute and the district court's grant of summary judgment of invalidity with respect thereto was appropriate.

IV.

Augustine Medical's cross-appeal further challenges the district court's grant of summary judgment of non-infringement with respect to the '188 patent. Claim 1 is the only disputed independent claim of the '188 patent. Claim 1 recites, in part, "an inflatable cover housing including a plurality of inflatable hollow tubes, each tube having a rounded upper portion and a flattened lower portion, joined in a substantially parallel array to form a substantially smooth lower cover surface."

After initially recommending against a grant of summary judgment, on March 15, 1996, the magistrate judge revisited that recommendation on July 18, 1997. In this later recommendation, the magistrate judge concluded that the accused blankets did not infringe the '188 patent claims literally or under the doctrine of equivalents.

Specifically, the magistrate judge concluded that the accused blankets did not literally contain tubes, a parallel array of chambers, a flattened lower cover surface, or a substantially smooth lower cover surface. The magistrate judge further concluded that the accused blankets lacked equivalents of these limitations.

Although, under the doctrine of equivalents, an element or limitation of the claim is not required to be literally present in the accused device, the accused device must still contain an equivalent of that element or limitation. See Warner-Jenkinson, 117 S. Ct. at 1054. In this case, the "flattened lower portion" is completely absent in the accused blankets. The "flattened lower portion" is not literally present because the accused blankets have a quilted lower surface nearly identical to their upper surface. The accused blankets also lack any feature equivalent to the "flattened lower portion."

To infringe under the doctrine of equivalents, the accused blankets must contain features which are insubstantially different than the claim elements. Insubstantial differences may be found where a structure performs substantially the same function in substantially the same way to achieve substantially the same result as the claim element. As explained in the specification, the "flattened lower portion" claim element functions together with the "rounded upper portion" to create a structure that avoids contact with the patient.

When the cover is placed over the patient and inflated, the pressure of one tube against another is collected at the edges of the cover which causes the edges to curl down around the patient toward the [bed] surface. . . . [T]he inflation of the tubes provides the cover with a self-supporting structure having a generally rounded or elliptical cross-sectional shape which contacts the patient only at the tubes which are immediately adjacent the keystone tube.

'188 patent, col. 4, ll. 7-16. The inclusion of both of these elements is necessary to have a "self-erecting structure" in which the patient can be bathed in the temperature controlled medium. Based on the undisputed facts, no reasonable jury could conclude that there are features of the accused blankets which are insubstantially different than the "flattened lower portion" limitation. The record shows that the accused blankets have nearly identical, quilted upper and lower surfaces and that the blankets rest on and maintain significant contact with the patient when inflated. Augustine Medical is unable to point to and we are unable to identify any features of the accused blankets which could function to create a "self-supporting structure" that avoids contact with the patient. Therefore, because the undisputed facts show that the accused blankets do not literally or equivalently contain every limitation of the '188 patent claims, there can be no infringement. Accordingly, the district court appropriately granted summary judgment of non-infringement with respect to the '188 patent.

V.

Finally, with respect to the district court's dismissal of Gaymar's claim of invalidity regarding the '417 patent, Augustine Medical dismissed with prejudice all claims against Gaymar related to the '417 patent and stipulated that none of Gaymar's products infringed the '417 patent. This court agrees with the district court that this stipulation and dismissal of claims with prejudice eliminated any potential case or controversy and thereby mooted Gaymar's claim of invalidity. This court finds Gaymar's assertions to the contrary unpersuasive.

VI.

Because prosecution history estoppel bars Augustine Medical from recapturing convective thermal blankets which are not "self-erecting," this court reverses the imposition of the Injunction against Gaymar and Mallinckrodt as well as the district court's refusal to grant JMOL of non-infringement. However, because this court concludes that no reasonable jury could find sufficient support for claims 1, 3, 4, and 8 of the '371 patent in the '757 application, this court affirms the district court's grant of summary judgment that these claims are invalid under § 102(b). Furthermore, because the district court did not err in construing the elements of the '188 patent claims or in applying the "all elements" rule of the doctrine of equivalents, this court affirms the district court's grant of summary judgment of non-infringement with respect to the '188 patent. Finally, because the district court appropriately determined that Gaymar's claim of patent invalidity with respect to the '417 was moot in light of the stipulations of fact entered by Augustine Medical, this court affirms that decision.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, REVERSED-IN-PART

**COMBINED PETITION FOR REHEARING AND SUGGESTION FOR
REHEARING IN BANC OF PLAINTIFF-CROSS-APPELLANT
AUGUSTINE MEDICAL, INC.**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

98-1001,
-1002, -1054, -1244, -1266

AUGUSTINE MEDICAL, INC.,

Plaintiff-Cross-Appellant,

v.

GAYMAR INDUSTRIES, INC.
and MEDISEARCH P R, INC.,

Defendants-Appellants,

and

MALLINCKRODT GROUP, INC.
and MALLINCKRODT MEDICAL, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the District of
Minnesota in 94-CV-875, 94-CV-888, 96-CV-347 and 96-CV-1145,
Judge James M. Rosenbaum

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June 21, 1999

CERTIFICATE OF INTEREST

Pursuant to Rule 47.4 of the Rules of this Court, Plaintiff-Cross-Appellant Augustine Medical, Inc. submits this Certificate of Interest as follows:

1. The full name of the party represented by counsel listed below is:
Augustine Medical, Inc.
2. Augustine Medical, Inc. is the real party in interest in this case.
3. Augustine Medical, Inc. has no parent companies, subsidiaries or affiliates that have issued shares to the public.
4. The names of all law firms and the partners or associates that have appeared for the parties now represented by the undersigned in the trial or who are expected to appear in this Court are:

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5. The names of attorneys that have appeared for the parties now represented by the undersigned who are no longer associated and/or affiliated with the undersigned firm are:

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Date: June 21, 1999

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STATEMENT OF COUNSEL

Based on my reasoned and studied professional judgment, I believe the panel decision is contrary to the following precedent of this Court: *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 48 U.S.P.Q.2d 1001 (Fed. Cir. 1998).

Based on my reasoned and studied professional judgment, I believe this appeal requires answer to one or more precedent-setting questions of exceptional importance: Whether the right to trial by jury granted in the Seventh Amendment to the Constitution of the United States is offended by the failure to give deference to the jury's determination of the scope of estoppel a reasonable competitor could rely on from a reading of the claims, specification and file history?


/s/ _____
ATTORNEY OF RECORD FOR
PLAINTIFF-CROSS-APPELLANT
AUGUSTINE MEDICAL, INC.

POINTS OF LAW OR FACT

- I. THE COURT DID NOT CONSIDER, AND ITS DECISION NOW CONFLICTS WITH, THE DIRECTLY APPLICABLE PRECEDENT OF *COMARK COMMUNICATIONS INC. V. HARRIS CORP.* THAT THE BURDEN IS ON THE APPELLANT TO SHOW EITHER THAT THE JURY COULD NOT REASONABLY FIND A PARTICULAR LIMITATION LITERALLY OR THAT THERE WAS NOT SUFFICIENT EVIDENCE ON EQUIVALENTS AS TO ANY ELEMENT.
- II. THIS PROCEEDING INVOLVES A QUESTION OF EXCEPTIONAL IMPORTANCE, NAMELY WHETHER THE JURY SHOULD BE AFFORDED ANY DEFERENCE AS TO THE FACTUAL INQUIRY OF WHAT A COMPETITOR WOULD REASONABLY CONCLUDE IN DETERMINING THE SCOPE OF ESTOPPEL.

FACTS RELEVANT TO BOTH PETITION AND SUGGESTION

I. TRIAL COURT PROCEEDINGS.

Appellee-Cross Appellant Augustine Medical, Inc. ("Augustine") brought an action for infringement of four patents directed to convective warming blankets against Appellants Gaymar Industries, Inc. ("Gaymar") and Mallinckrodt Group, Inc. ("Mallinckrodt"). Addendum ("Add.") at 3. The patents in suit are U.S. Patent Nos. 5,300,102 ("the '102 patent"), 5,324,320 ("the '320 patent"), 5,405,371 ("the '371 patent") and 4,572,188 ("the '188 patent"). Add. at 3. The patented convective warming blankets are used before, during and after surgery to control a patient's body temperature by bathing the patient in circulating warm air. Add. at 4. At trial, all elements of Augustine's claims were disputed and

submitted to the jury including “self-erecting,” “discontinuous seams” attaching the upper and lower sheets of the blankets, and “chambers.”

The trial court instructed the jury that “self-erecting” means the inflated blanket forms a “curved or arched structure which stands off the patient.” Add. at 9; JA04184 ll. 4-6. The trial court had denied Appellants’ motions for summary judgment with respect to the “self-erecting” limitation, ruling it is a jury question of whether the accused blankets literally self-erect. Add. at 9. Augustine put on a case of literal and equivalent infringement. Appellants conceded at trial that a “self-erecting” blanket can contact the patient at some points, but argued that the accused blankets exhibited too much contact to meet the self-erecting limitation literally. Thus, a substantial fact question for the jury was whether, in operation, the accused blankets “stand off” the patient.

At Appellants’ request, the jury was instructed to consider the scope of any prosecution history estoppel. JA04186-04187 ll. 20-5. The jury returned a general verdict of infringement of numerous claims of the ‘102, ‘320 and ‘371 patents under the doctrine of equivalents. Add. at 11. The verdict form did not specify which elements were found literally and which were found equivalently. JA00018-00028A.

II. APPEAL.

Gaymar and Mallinckrodt appealed, arguing prosecution history estoppel as to the claim element “self-erecting” and challenging the sufficiency of the evidence of equivalence as to all elements. Mallinckrodt Brief at pp. 32-39, 42-49; Gaymar Brief at 25-45. Appellants did not appeal the trial court’s definition of “self-erecting,” namely, “forms a curved or arched structure which stands off the patient.” Add. at 9.

This Court quoted with approval the trial court’s claim definition “forms a curved or arched structure that stands off the patient.” Add. at 11. This Court observed that the magistrate judge noted that “the Mallinckrodt blanket move[d] slightly away from the person underneath it and assume[d] a shape over the person” when in operation, and the Gaymar “blanket lift[ed] slightly away from the table as it [was] inflated.” Add. at 8. Finally, this Court noted that the trial court found an issue of fact which was submitted to the jury as to whether the accused blankets self-erect literally. Add. at 9.

Although many elements were disputed and there was no special verdict form specifying how each element was met, this Court implicitly concluded that the jury did not find the “self-erecting” limitation literally and ruled that prosecution history estoppel precluded a finding of “self-erecting” by equivalents.

Add. at 4 & 11. It appears that this Court further construed “self-erecting” to include the additional limitation “self-supporting,” which appears in dependent claim five of the ‘188 patent, and ruled that the accused blankets are not literally “self-supporting” as a matter of law. Add. at 11.

The Detailed Description Of The Preferred Embodiments in the ‘188 patent describes a “self-supporting” blanket as one where “the edges curl down around the patient” such that the blanket “contacts the patient only at the tubes which are immediately adjacent to keystone tube.” JA04302 col. 4 ll. 7-16. The specifications of the other patents-in-suit note that “tubes are preferred since they impart shape and strength to the erected bathing structure; other inflatable structures are contemplated, however.” (Emphasis added.) JA04430 col. 4 ll. 63-66; JA04631 col. 4 ll. 33-36; JA05038 col. 5 ll. 31-34.

This Court did not explicitly address literal claim scope, nor did it address the open question of literal infringement. Furthermore, this Court chose to disregard its recent precedent in *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 1187, 48 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1998) pertaining to jury verdicts under the doctrine of equivalents where no special interrogatory is used to show which elements are found equivalently and which are found literally.

Consequently, Augustine has filed this combined petition for rehearing and suggestion for rehearing in banc.

ARGUMENT -- PETITION FOR REHEARING

I. **THIS COURT'S DECISION IN COMARK COMMUNICATIONS INC. V. HARRIS CORP. IS DIRECTLY ON POINT AND MUST BE CONSIDERED.**

The jury rendered a verdict of infringement of the asserted claims, but did not specify which limitations were met by equivalents. Thus the record does not reveal whether the particular limitation of "self-erecting" was found literally or equivalently. Following the close of briefing in this case, this Court decided *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 1187, 48 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1998). This Court articulated the following rule:

Where there is no specific finding by the jury of equivalence as to a particular element, and the defendant has not successfully argued that a particular limitation could not be met literally, the defendant has assumed the burden of proving not only that there is insufficient evidence under *Lear Siegler* for a jury to find that the limitation could be met equivalently, it must also establish that there is no substantial evidence in the record that would permit the jury to find that any limitation has been met by equivalents.

Comark, 156 F.3d at 1189, 48 U.S.P.Q.2d at 1006 (emphasis in original). Thus, in this case, Gaymar and Mallinckrodt must show either that the jury could not have found that the accused blankets literally "self-erect" or that there was not

sufficient evidence on equivalence as to any limitation. If they cannot, this Court must uphold the jury verdict. *See id.* at 1188, 48 U.S.P.Q.2d at 1006.

A. Neither Gaymar Nor Mallinckrodt Satisfied Its Burden Under *Comark*.

Gaymar and Mallinckrodt did not argue on appeal that the jury could not have found that their blankets literally self-erect. Nor did they dispute the trial court's instruction that self-erecting means the blanket "forms a curved or arched structure which stands off the patient." Add. at 11. Instead, Appellants focused their argument on the sufficiency of the evidence to support a finding of infringement as to any of the five disputed elements under the doctrine of equivalents. This Court did not analyze and should not reasonably find that the self-erecting limitation could not literally have been met under the instruction given, nor did this Court rule that there was insufficient evidence to find any element by equivalents.

B. The Record Demonstrates That The Jury Could Have Found Literal Infringement Of The "Self-Erecting" Limitation.

This Court noted the following evidence in the record:

With respect to the other patents, the magistrate judge detected a genuine issue of material fact relative to the "self-erecting" limitation. Specifically, the magistrate judge noted that "the Mallinckrodt blanket move[d] slightly away from the person underneath it and assume[d] a shape over the person" when in operation. When considering the Gaymar blanket, the magistrate judge explained that "the blanket lift[ed] slightly away from the table as it [was] inflated."

Add. at 8. Based on this evidence, both the magistrate and the trial court “identified the same issue of material fact regarding whether Gaymar’s and Mallinckrodt’s blankets literally or equivalently self-erect.” *Id.* at 9 (emphasis added). The trial court submitted literal and equivalent infringement to the jury and this Court did not find any fault with the charge to the jury regarding the definition of self-erecting; in fact, this Court affirmed the trial court’s claim definition: “the district court correctly construed the term ‘self-erecting’ to require that the accused blankets form a curved or arched structure which stands off the patient.” Add. at 11. The jury properly could have found literal self-erecting because when the accused blankets are inflated over a patient, they “move slightly away from the person,” and the “shape” that they assume is literally “a curved or arched structure which stands off the patient.”

C. The Literal Scope Of “Self-Erecting” Was Not And Should Not Be Limited To The Scope Of Dependent Claims Directed To A “Self-Supporting” Blanket.

This Court apparently misapprehended the jury’s general verdict of equivalents to have been a verdict specifically directed to the self-erecting limitation. If not, then the Court must have assumed that either (i) none of the other disputed limitations could have been found equivalently as opposed to literally, or (ii) that “forming a curved or arched structure which stands off the

patient” means the same as “self-supporting.” As to the other disputed elements, days of trial were devoted to Appellants’ arguments that they did not have “seams” and “chambers” and to Augustine’s showing that the accused blankets had at least the equivalents of seams and chambers. Augustine’s Principal Brief at 19-29. Any of these other disputed elements easily could have been found by equivalents.

This Court should not rule that “forming a curved or arched structure which stands off the patient” means “self-supporting” or “does not touch the patient.” This construction would be contrary to the one adopted by the trial court and nominally approved by this Court, and would violate the doctrine of claim differentiation. *See Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1277, 35 U.S.P.Q.2d 1035, 1041 (Fed. Cir. 1995). The term “self-supporting,” which may reasonably be construed to prohibit contact with the patient, is a limitation of dependent claim five of the ‘188 patent. The independent claims, which lack the limitation “self-supporting,” should not be read to have the same scope. The parties did not brief or argue this issue of claim differentiation because the Appellants did not contest the trial court’s definition.

Other dependent claims in the other patents make it clear that the tubes needed to form a self-supporting blanket are not a limitation of the asserted

independent claims. For example, claim 1 of the '102 patent is directed to a plurality of "chambers" rather than tubes. Dependent claim 10 adds the limitation of "mutually parallel, communicating tubular chambers." The specifications of each of the patents further note that "tubes are preferred since they impart shape and strength to the erected bathing structure; other inflatable structures are contemplated, however." (Emphasis added.) JA04430 col. 4 ll. 63-66; JA04631 col. 4 ll. 33-36; JA05038 col. 5 ll. 31-34. The clear teaching is that neither shape nor strength nor tubes -- the hallmarks of a self-supporting blanket -- are limitations of the independent claims.

Although Augustine argued for an even broader reading of self-erecting -- simple inflation of the blankets under air pressure alone -- to show that JMOL might have been required in Augustine's favor, no party suggested on appeal that the literal scope of self-erecting should be as narrow as self-supporting. Augustine merely pointed out that under a broader construction of "self-erecting," this Court might find the "self-erecting" limitation literally met as a matter of law and might find that all of the other disputed limitations were literally or equivalently present as a matter of law. The only narrow definition of "self-erecting" that still respects claim differentiation is the one given by the trial court

-- and not "self-supporting" -- which renders literal presence of the self-erecting element a question of fact properly submitted to the jury.

D. A Rehearing Is Necessary To Consider The Question Of Literal Infringement Of The Claim Limitation "Self-Erecting" Based On The Record.

Under *Comark*, this Court "cannot presume to ascertain which elements the jury found to be met only by equivalents." *Comark*, 156 F.3d at 1188, 48 U.S.P.Q.2d at 1006. This Court did presume that the jury in this case found infringement of the term self-erecting only by equivalents. Because this Court did not address literal infringement in its opinion, a rehearing is necessary.

ARGUMENT - SUGGESTION FOR REHEARING IN BANC

I. THE PANEL'S DECISION IS IN CONFLICT WITH THIS COURT'S DECISION IN COMARK COMMUNICATIONS INC. V. HARRIS CORP. REGARDING JURY VERDICTS WHERE THE VERDICT FORM DOES NOT STATE WHETHER A PARTICULAR LIMITATION WAS FOUND LITERALLY OR EQUIVALENTLY.

As fully explained in the Petition for Rehearing Argument Part I, *supra*, this Court's decision in *Comark* applies when a jury returns a verdict of infringement by the doctrine of equivalents and the verdict form does not state which elements were found literally and which were found equivalently. *Comark Communications Inc. v. Harris Corp.*, 156 F.3d 1182, 1187, 48 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1998). The decision of the panel in the present case assumes, without proof of any kind, that a particular limitation was found equivalently.

The decision in *Comark* is correct. The Court must uphold jury verdict's of the nature in question "if there is sufficient evidence of equivalents and linking testimony such that a reasonable jury could have found that at least one element was met by equivalents." *Comark*, 156 F.3d at 1188, 48 U.S.P.Q.2d at 1006. Otherwise the Court is only guessing as to what the jury found. A rehearing in banc is necessary to ensure consistency in the application of the rule announced in *Comark* and to avoid confusion and uncertainty among the trial bench and bar.

II. WHETHER THE SCOPE OF PROSECUTION HISTORY ESTOPPEL SHOULD BE DECIDED AS A MATTER OF LAW OR OF FACT IS A QUESTION OF EXCEPTIONAL IMPORTANCE.

Appellants put into evidence the application and scope of prosecution history estoppel in this case, including the nature of the doctrine, the statements creating an estoppel in this case and the scope of the estoppel. Trial Transcript, August 20, 1997, pp. 52-55 ll. 19-21; Trial Transcript, August 21, 1997, pp. 122-123 ll. 24-9; JA03960-03961 ll. 20-9. They argued the scope of estoppel to the jury in detail. At their request, the jury was instructed to consider whether Augustine could prevail consistently with the statements in the file history. The specific instruction given is as follows:

- 19 The history of the prosecution of the patent
- 20 application, that's called the file record or the written
- 21 correspondence, for the applicant to the patent office is
- 22 used to explain the meaning of the words used in the patent

23 claims. That's the file, wrapper, stuff you've been given.
24 A patent owner is estopped, you know the legal term, is
25 prevented from taking a position that is inconsistent with

197

1 the positions that the patentee took when attempting to
2 convince the patent trademark office to issue the patent.
3 This is called the document prosecution history
4 estoppel.

JA04186-04187 ll. 20-5. Thus, Appellants specifically asked the jury to make a factual finding as to the existence and scope of any estoppel. Having lost their gamble with the jury, Appellants now seek a second bite at the apple.

A. The Jury's Verdict Included The Jury's Consideration Of Estoppel And It Cannot Be Set Aside Without Offending The Seventh Amendment To The United States Constitution.

This Court and the Supreme Court have clearly established that the Seventh Amendment to the United States Constitution preserves the right of jury trial in patent cases. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S. Ct. 1384, 1389 (1996); *Paltex Corp. v. Mossinghoff*, 758 F.2d 594 (Fed. Cir. 1985). This Court has also explained that the scope of prosecution history estoppel depends upon a fact finding: what a reasonable competitor is entitled to conclude from a reading of the file history. *Haynes International Inc. v. Jessop Steel Co.*, 8 F.3d 1573, 28 U.S.P.Q.2d 1652 (Fed. Cir. 1993), *on reh'g*, 15 F.3d 1076, 29 U.S.P.Q.2d 1958 (Fed. Cir. 1994); *see also Modine Mfg. Co. v. U.S. Intern. Trade*

Com'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996), *cert. denied*, 116 S. Ct. 1523 (1996) (explaining that the standard for determining the scope of estoppel is based on the reasonable reading, by a person of skill in the field of the invention, of the entire prosecution history). Where, as here, the jury is instructed to consider and rule on factual predicates to legal issues and returns a general verdict unaccompanied by the specific fact finding, the verdict includes the fact finding by necessary implication. *E.g.*, *DMI, Inc. v. Deere & Co.*, 802 F.2d 421 (Fed. Cir. 1986). In short, the jury's verdict in this case necessarily included a fact finding that reasonable competitors are not entitled to conclude that the scope of any estoppel surrendered the subject matter of the accused blankets.

The panel substituted its judgment for that of the jury with respect to the underlying factual predicate that determines the scope of estoppel. Although this Court has often announced that prosecution history estoppel is an issue of law for the court, counsel has found no specific guidance as to the jury's role in the specific factual predicate underlying the scope of estoppel. The patent bar and the trial bench would benefit substantially from consideration by this Court in banc whether juries should be permitted to consider the underlying factual question of what reasonable competitors may conclude from file histories and from clarification of what the legal standard for trial judges and on review should be,

when juries are asked to and find the scope of estoppel does not extend to the accused equivalent.

Moreover, having ruled that factual issues in patent cases are the subject of the right to jury trial, and having announced that the test for estoppel is a question which clearly depends on underlying factual questions, this Court has left uncertain the role of the Seventh Amendment in cases of prosecution history estoppel. Upon reconsideration in banc, Augustine would urge that the right to jury trial should include the underlying factual question of the scope of estoppel. Counsel would show that under the present state of the Court's jurisprudence, the right to jury trial in patent cases is materially diminished by de novo review in all cases, regardless of the basis for the jury's verdict.

CONCLUSION

For the foregoing reasons, Augustine Medical, Inc.'s petition for rehearing and suggestion for rehearing in banc should be granted.

Date: June 21, 1999

OPPENHEIMER WOLFF & DONNELLY LLP

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**ATTORNEYS FOR PLAINTIFF-CROSS-
APPELLANT AUGUSTINE MEDICAL, INC.**

United States Court of Appeals for the Federal Circuit

98-1001,
-1002, -1064, -1244, -1266

AUGUSTINE MEDICAL, INC.,

Plaintiff-Cross Appellant,

v.

GAYMAR INDUSTRIES, INC.
and MEDISEARCH P R, INC.,

Defendants-Appellants,

and

MALLINCKRODT GROUP, INC.
and MALLINCKRODT MEDICAL, INC.,

Defendants-Appellants.

J. Randall Benham, Augustine Medical, Inc., of Eden Prairie, Minnesota, argued for plaintiff-cross appellant. With him on the brief were Jacob M. Holdreith, Craig J. Lervick, and Robert M. Rauker, Oppenheimer Wolff & Donnelly LLP, of Minneapolis, Minnesota.

Robert J. Lane, Jr., Hodgson, Russ, Andrews, Woods & Goodyear, LLP, of Buffalo, New York, argued for defendants-appellants Gaymar Industries, Inc., et al.

Raymond A. Kurz, Rothwell, Figg, Ernst and Kurz, of Washington, D.C., argued for defendants-appellants Mallinckrodt Group, Inc., et al. With him on the brief was G. Franklin Rothwell.

Appealed from: U.S. District Court for the District of Minnesota

Judge James M. Rosenbaum

This USPTO date stamp hereon will acknowledge receipt of:

COMMUNICATION

Applicant: Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: 04/10/95

Enclosures: Transmittal Form; copies of Notice, Request
Form For Filing A Patent Application Under 37
CFR 1.60, Filing Receipt; and one return
postcard.

Mailed: *1 March 1999*

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Applicant: Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
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CFR 1.60, Filing Receipt; and one return
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Mailed: *1 March 1999*

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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	08/419,719	
	Filing Date	04/10/95	
	First Named Inventor	Augustine et al	
	Examiner Name	Graham	
	Group Art Unit	3304	
Total Number of Pages in This Submission	7	Attorney Docket Number	AUGA01000010

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Response <input type="checkbox"/> After Final <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> PTO Form 1449 <input type="checkbox"/> (no.) cited references <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> PTO Form 1533 <input type="checkbox"/> Response to Missing Parts Under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition Checklist and Accompanying Petition <input type="checkbox"/> To Convert a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below): <u>POSTCARD</u> <hr/> <hr/>
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual Name	Terrance A. Meador Reg. No. 30,298 GRAY CARY WARE & FREIDENRICH
Signature	<i>Terrance A. Meador</i>
Date	<i>MARCH 1999</i>

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Signature	<i>Terrance A. Meador</i>	Date	<i>MARCH 1999</i>

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
S.D. AUGUSTINE ET AL.)	Group Art Unit: 3304
)	
Serial No.: 08/419,719)	
)	
Filed: April 10, 1995)	Examiner: M. Graham
)	
For: THERMAL BLANKET)	

Assistant Commissioner for Patents
Washington, D.C. 20231

ATTN: Mark Graham

Sir:

COMMUNICATION

On June 2, 1997, a Notice (Paper No. 19) was mailed from the Office of Patent Publication to the undersigned. A copy of the paper is attached. The purpose of the Paper was to give notice that the subject patent application was withdrawn from issue by the Office for the purpose of reopening prosecution. The Notice indicated the application was being returned to the Office of the Director of Group 3300. Since the June 2, 1997 Notice, we have received no further communication from the Patent Office regarding this matter.


On May 21, 1997, a Rule 60 Continuation was filed in this application. A copy of the Continuation Request is also attached. The Official Filing Receipt for this Continuation, copy attached, indicated that the subject application, Serial No. 08/419,719 had been abandoned. As evidenced by the Continuation Request, no abandonment was requested.

The undersigned respectfully requests information as to the status of this application and the location of its file.

Respectfully submitted,

Date:

1 March 1999


TERRANCE A. MEADOR
Reg. No. 30,298

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401 B Street, Suite 1700
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Telephone (619) 699-2652 Fax (619) 236-1048

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Baker, Maxham, Jester & Meador



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Patent and Trademark Office
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Washington, D.C. 20231

Paper No. 19

TERRANCE A. MEADOR
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SYMPHONY TOWERS
750 "B" STREET, SUITE 3100
SAN DIEGO, CALIFORNIA 92101

COPY MAILED

JUN 02 1997

OFFICE OF
PATENT PUBLICATION

In re Application of
Scott D. Augustine, et al.
Application No. 08/419,719
Filed: April 10, 1995
Attorney Docket No. 1342-119

NOTICE

The purpose of this communication is to inform you that the above - identified application, which has received a patent number or an issue date, is being withdrawn from issue pursuant to 37 CFR 1.313.

The application is being withdrawn for the following purpose: to reopen prosecution. This withdrawal was requested by the Group Director. Any questions concerning this withdrawal should be addressed to the Group Director.

This application is being returned to the Office of the Director of Group 3300.

Telephone inquiries concerning this matter may be directed to the undersigned at (703) 308-5254.

Karna Cooper
Paralegal Specialist
Office of the Director
Office of Patent Publication

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JUN - 4 1997

FILE 842-119 *k*

9. Priority of foreign application number , filed on in is claimed under 35 U.S.C. 119.

 The certified copy has been filed in prior application number / , filed .

10. A preliminary amendment is enclosed.

11. X The prior application is assigned of record to AUGUSTINE MEDICAL, INC.

12. X Also enclosed: (7) Information Disclosure Statements & PTO Form 1449's from the parent case Serial No. 08419,719, filed April 10, 1995.

13. X The power of attorney in the prior application is to: (named & address):

Terrance A. Meador, #30,298
BAKER, MAXHAM, JESTER & MEADOR
110 West "C" Street, Suite 1202
San Diego, California 92101

- a. X The power of attorney appears in the original papers in the prior application.
b. Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
c. X Address all future correspondence to: (May only be completed by applicant, or attorney or agent of record.)

Terrance A. Meador, #30,298
BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

21 May 1997
Date

 Inventor(s)
 Assignee of complete interest
 X Attorney or agent of record
 Filed under 37 CFR 1.34(a)
 Registration number if acting under 37 CFR 1.34(a).

Terrance A. Meador
Signature

TERRANCE A. MEADOR, #30,298
Typed or printed name (& registration number if applicable)

FD-36 (Rev. 5-81)

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APPLICATION NUMBER	FILING DATE	GRP/ART/UNIT	FILED REC.DY	ATTORNEY DOCKET NO.	DRWGS	FIGS	IND. CL.
08/359,391	05/21/97	3311	\$640.00	1342-188	5	25	9

TERRANCE A. MEADOR
BAKER MAXHAM JESTER & MEADOR
SYMPHONY TOWERS
750 B STREET, SUITE 3100
SAN DIEGO CA 92101

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this filing receipt, please write to the Application Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the filing receipt with the changes noted thereon.

Applicant(s)

SCOTT D. AUGUSTINE, BLOOMINGTON, MN; RANDALL G. ARNOLD, MAPLEWOOD, MN

CONTINUING DATA AS CLAIMED BY APPLICANT

THIS APPLN IS A CON OF 08/419,719 04/10/95 ABN
WHICH IS A CIP OF 07/550,757 07/10/90
WHICH IS A CIP OF 07/227,189 08/02/88
WHICH IS A CIP OF 07/104,682 10/05/87 ABN

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PRELIMINARY CLASS 607

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent Application Serial No. 08/419,719

Filed: 4-10-95

Inventor: Augustine, et al

Group: 3304

Examiner: A. Graham

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

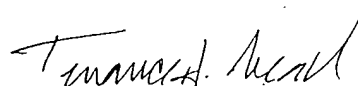
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REQUEST FOR CHANGE OF ADDRESS

This is to notify the Office that all correspondence in the subject matter should be addressed to:

TERRANCE A. MEADOR
GRAY CARY WARE & FREIDENRICH
4365 EXECUTIVE DRIVE, SUITE 1600
SAN DIEGO, CA. 92121-2189

RESPECTFULLY SUBMITTED


Terrance A. Meador
Registration No. 30,298

The USPTO date stamp hereon acknowledges receipt of:

INFORMATION DISCLOSURE STATEMENT For "Inflatable Lower Body Thermal Blanket" (2 pgs. + a copy)

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995

Enclosures: PTO Form 1449
Cited references
a check for \$240

Mailed: November 17, 1997

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1342-119



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Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995

PTO Form 1449
Cited references
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 Case
 1342119
 Amount
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11/17/97 Total Paid 240.00

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"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
S.D. AUGUSTINE, ET AL.)	Group Art Unit: 3304
Serial No.: 08/419,719)	
Filed: April 10, 1995)	Examiner: M. Graham
For: INFLATABLE LOWER BODY)	
THERMAL BLANKET)	

Assistant Commissioner for Patents
Washington, D.C. 20231

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Date	Signature

INFORMATION DISCLOSURE STATEMENT

Applicant hereby cites the documents listed in accompanying Form PTO-1449 with respect to the above-referenced patent application under the provisions of 37 C.F.R., Sections 1.56, 1.97 and 1.98. Copies of the documents are attached.

This information is submitted in order to keep the Examiner apprised of the status of U.S. Patent No. 5,405,371, which issued from a predecessor application - No. 638,748, filed 8 January 1991.

A check in the amount of \$240 is enclosed in accordance with § 1.97(c) is enclosed. Please charge or credit Deposit Account 02-0460 any discrepancy. A duplicate of this paper is enclosed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Terrance A. Meador", with a stylized flourish at the end.

TERRANCE A. MEADOR
Reg. No. 30,298

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"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
S.D. AUGUSTINE, ET AL.)	Group Art Unit: 3304
Serial No.: 08/419,719)	
Filed: April 10, 1995)	Examiner: M. Graham
For: INFLATABLE LOWER BODY)	
THERMAL BLANKET)	

Assistant Commissioner for Patents
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Date	Signature

INFORMATION DISCLOSURE STATEMENT

Applicant hereby cites the documents listed in accompanying Form PTO-1449 with respect to the above-referenced patent application under the provisions of 37 C.F.R., Sections 1.56, 1.97 and 1.98. Copies of the documents are attached.

This information is submitted in order to keep the Examiner apprised of the status of U.S. Patent No. 5,405,371, which issued from a predecessor application - No. 638,748, filed 8 January 1991.

A check in the amount of \$240 is enclosed in accordance with § 1.97(c) is enclosed. Please charge or credit Deposit Account 02-0460 any discrepancy. A duplicate of this paper is enclosed.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Terrance A. Meador", with a stylized flourish at the end.

TERRANCE A. MEADOR
Reg. No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 B Street, Suite 3100
San Diego, California 92101

Telephone (619) 233-9004

Fax (619) 544-1246

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Reexamination of U.S. Patent No.)	
	5,405,371)	
Inventors:	S. D. Augustine et al.)	
Control No:	90/004,529)	
Filed :	January 23, 1997)	Group Art Unit: Special Program
Title:	THERMAL BLANKET)	Law Office
Docket No:	8847/300)	Examiner: L. Anderson

Commissioner of Patents and Trademarks
Washington, D.C. 20231

I hereby certify that this Communication to Examiner was
transmitted by facsimile to the Commissioner of Patents
and Trademarks, Washington, D.C. 20231, on October
21, 1997.


Rita M. McAloon, Secretary to Craig J. Lervick

COMMUNICATION TO EXAMINER

Dear Sir:

The following is an update pursuant to 37 C.F.R. 1.565(a).

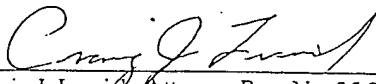
In the cases of Augustine Medical, Inc. v. Gaymar Industries, Inc. et al. and Augustine Medical, Inc. v. Mallinckrodt Medical, Inc. et al. (the "litigation"), which has previously been identified in this proceeding, judgment in favor of Augustine Medical, Inc. was entered on September 26, 1997. By so entering judgment, the Court incorporated all previous orders and findings into its final judgment, including, but not limited to: (1) the January 28, 1997 order granting of defendant's motion for summary judgment of invalidity of claims 1, 3, 4 and 8 of U.S. Patent No. 5,405,371, and (2) the jury's verdict finding valid, enforceable and infringed

claims 2, 5, 6, 7, and 9 of U.S. Patent No. 5,405,371. The time period for appeal from this judgment has not yet passed.

Respectfully submitted,

S. D. AUGUSTINE et al., Applicants

Date: October 21, 1997



Craig J. Lervick, Attorney Reg. No. 35,244
Oppenheimer Wolff & Donnelly
3400 Plaza VII
45 South Seventh Street
Minneapolis, Minnesota 55402
Telephone: (612) 607-7387
Fax: (612) 607-7100
Attorney for Applicants

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the following correspondence is being transmitted by facsimile to the Patent and Trademark Office on the date shown below.

1. Communication to Examiner.

Rita M. McAloon
Signature Rita M. McAloon

October 21, 1997
Date

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OCT 31 1997

Baker, Maxham, Jester & Meador



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

LEA/GAD

Terrance A. Meador
Baker Maxham Jester & Meador
Symphony Towers Suite 3100
750 B Street
San Diego, CA 92101

(For Patent Owner)

MAILED

OCT 28 1997

REEXAM UNIT

In re reissue application of
Augustine, et al.
Serial No. 08/658356
Filed: June 5, 1996
For: U.S. Patent No. 5,405,371 : DECISION, SUA SPONTE, TO MERGE
: REEXAMINATION AND
In re Augustine, et al. : REISSUE PROCEEDINGS
: Reexamination Proceeding
Control No. 90/004,529
Filed: January 23, 1997
For: U.S. Patent No. 5,405,371 :

The above noted reexamination file and reissue application are before the Office of the Deputy Assistant Commissioner for Patent Policy and Projects, sua sponte, for a decision on whether the proceedings should be merged at this time.

REVIEW OF FACTS

- 1) U.S. Patent No. 5,405,371 issued April 11, 1995.
- 2) On June 5, 1996, a reissue application was filed by the patent owner. In the reissue, Patent Owner deleted the words "self-erecting" from claims 1, 4, 8 and 9. He also added dependent claims 10-20.
- 3) In an Office action dated October 28, 1996, the examiner rejected claims 1-9 based on a defective reissue declaration. Claims 10 - 20 are not commented upon.

DOCKETED

1342-352

- 4) On November 18, 1996, in related litigation in the United States District Court, District of Minnesota, Fourth Division, Case Nos. 4-94-CV-875, et al., in response to a defendant's motion for summary judgement, claims 1, 3, 4, and 8 were recommended as being invalid by the Magistrate Judge.
- 5) On January 10, 1997, a request for reexamination of the patent was filed by the patent owner.
- 6) On January 28, 1997, the decision of the Magistrate Judge was adopted by the District Court which found claims 1, 3, 4 and 8 of the '371 patent to be invalid.
- 7) On April 9, 1997, reexamination was ordered on the basis that there was a significant question of patentability concerning claims 1, 3, 4 and 6, and additionally the claims 2, 5 and 7 - 9.
- 8) On April 22, 1997, in the reissue application, an Office action issued suspending prosecution for four months.
- 9) On September 26, 1997, in the cases of *Augustine Medical, Inc. v. Gaymar Industries, Inc.* and *Augustine Medical, Inc. v. Mallinckrodt Medical, Inc.*, the United States District Court, District of Minnesota, Fourth Division, entered judgment in favor of Augustine Medical, Inc. (Patent Owner). By so entering judgment, the District Court incorporated all previous orders and findings into its final judgment, including the January 28, 1997 order granting defendant's motion for summary judgment of invalidity of claims 1, 3, 4 and 8 of the '371 patent and the jury's verdict finding valid, enforceable and infringed claims 2, 5, 6, 7 and 9 of the '371 patent.

DISCUSSION

Under 37 CFR § 1.565(d):

- (d) If a reissue application and a reexamination proceeding on which an order pursuant to § 1.525 has been mailed are pending concurrently on a patent, a decision will normally be made to merge the two proceedings or to stay one of the two proceedings....

As evidenced by the above review of facts, the reissue application and the reexamination proceeding are currently pending. As the order to reexamine has been mailed in the reexamination proceeding, a decision under § 1.565(d) is timely.

The general policy of the Office is that a reissue application examination and a reexamination proceeding will not be conducted separately at the same time as to a particular patent. The reasons for this policy is to prevent inconsistent, and possible conflicting amendments from being introduced into the two proceedings on behalf of the patent owner. Normally the proceedings will be merged whenever it is desirable to do so in the interest of expediting the prosecution of

both proceedings. In making a decision on whether or not to merge the two proceedings consideration will be given to the status of each proceeding. See MPEP 2285.

A review of the reissue prosecution history shows that the announcement of the filing of the reissue application was published in the Official Gazette on January 28, 1997, thereby permitting the issuance of a first action on the merits after March 28, 1997. 37 CFR § 1.176. New claims have been added in the reissue application. A review of the reexamination file shows that the reexamination is awaiting an Office action by the examiner. The original specification, drawings and patent claims are presently in the reexamination file. The claims are not identical in both proceedings. In order to provide efficient and prompt handling of both proceedings and to prevent inconsistent, and possibly conflicting amendments from being introduced on behalf of the patent owner, it is appropriate that the reissue and the reexamination proceeding be merged and a joint examination be conducted. Accordingly, the examination of the reissue application and the reexamination will be in accordance with the decision set forth below.

DECISION

I. Merger of Proceedings

The above noted reissue and reexamination proceedings are, sua sponte, merged. A joint examination will be conducted in accordance with the following guidelines and requirements.

II. Requirement for Same Amendments in Both Proceedings

The patent owner is required to maintain identical amendments in the reissue application and the reexamination file for purposes of the merged proceedings. The maintenance of identical amendments in the two files is required as long as the proceedings are merged. See 37 CFR § 1.565(d). An appropriate housekeeping amendment is required within one month of this decision placing the same amendments in both proceedings. The patent owner should not address the issues of either proceeding in the housekeeping amendment.

III. Conduct of the Merged Reissue Application Examination and Reexamination Proceeding

In view of the fact that the statutory provisions for reissue application examination include, inter alia, provisions equivalent to 35 U.S.C. § 305 relating to the conduct of reexamination proceedings, the merged examination will be conducted on the basis of the rules relating to the broader reissue application examination. The examiner will apply the reissue statute, rules and case law to the merged proceeding. The examiner's actions will take the form of a single action which jointly applies to both the reissue application and the reexamination proceeding. The action will contain identifying data for both the reissue application and the reexamination proceeding and will be physically entered into both files which will be maintained as separate files. Any response by the applicant/patent owner must consist of a single response, filed in duplicate, each bearing an

original signature, for entry in both files. Any such responses must be served on the requester who will also be sent copies of Office actions. See 37 CFR § 1.550(e).

If the applicant/patent owner fails to file a timely and appropriate response to any Office action, the merged proceeding will be terminated. The reissue application will be held abandoned and the Commissioner will proceed to issue a reexamination certificate under § 1.570 in accordance with the last action of the Office unless further action is clearly needed in view of the difference in rules relating to reexamination and reissue proceedings.

If the applicant/patent owner files an express abandonment of the reissue application pursuant to 37 CFR § 1.138, the next Office action of the examiner will accept the express abandonment, dissolve the merged proceeding and continue the reexamination proceeding. Any grounds of rejection which are not applicable under reexamination should be withdrawn (e.g., based on public use or sale) and any new grounds of rejection which are applicable under reexamination (e.g., improper broadened claims) should be made by the examiner upon dissolution of the merged proceeding. The existence of any questions remaining which cannot be considered under reexamination following dissolution of the merged proceeding would be noted by the examiner as not being proper under reexamination pursuant to 37 CFR § 1.552(c).

If the reissue application ultimately matures into a reissue patent the reexamination proceeding shall be terminated by the grant of the reissued patent and the reissued patent will also serve as the certificate under § 1.570. See MPEP 2285.

Applicant/patent owner is advised that the filing of (a) a file wrapper continuation (FWC) reissue application under 37 CFR § 1.62 or (b) a continued prosecution (CPA) reissue application under 37 CFR § 1.53 (d), whereby (in either case) the current reissue application is considered to be expressly abandoned, will most likely result in the dissolution of the merged proceeding, a stay of the FWC or CPA reissue application, and separate, continued prosecution of the reexamination proceeding.

It is noted that in the decision of *Ethicon v. Quigg*, 7 USPQ2d 1152, 1157 (Fed. Cir. 1988) the Court of Appeals for the Federal Circuit stated:

... [I]f a court finds a patent invalid, and that decision is either upheld on appeal or not appealed, the PTO may discontinue its reexamination. This is consistent with *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 [169 USPQ 513](1971), which "held that where a patent has been declared invalid in a proceeding in which the 'patentee has had a full and fair chance to litigate the validity of his patent' (402 U.S. at 333 [169 USPQ at 521] ...), the patentee is collaterally estopped from relitigating the validity of the patent." *Mississippi Chemical Corp. V. Swift Agricultural Chemicals Corp.*, 717 F.2d 1374, 1376, 219 USPQ 577, 579 (Fed. Cir. 1983), quoted in *Allen Archery*, 819 F.2d at 1091, 2

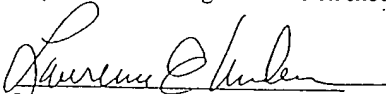
USPQ2d at 1492. Of course, in the end it is up to a court, not the PTO, to decide if the patentee had a "full and fair chance" to litigate the validity of the patent. But it is admissible for the PTO to act on the standing judgment of invalidity unless and until a court has said it does not have res judicata effect.

Accordingly, the patent claims 1, 3, 4 and 8 finally held invalid by the Federal court will be withdrawn from consideration on the grounds of collateral estoppel. The same will hold true for claims of the same or broader scope as those held to be invalid. With respect to claims raising issues not raised by the litigated claims, the Examiner will follow the analysis set forth by the Court of Appeals for the Federal Circuit in the case of *Interconnect Planning Corporation v. Feil*, 227 USPQ 543,546 (Fed. Cir. 1985). On the other hand, in accordance with MPEP 2242, the finding of *validity* by the District Court "does not necessarily mean that no new question is present, because of the different standards of proof employed by the Federal Courts and the Office." See *Ethicon v. Quigg*, 7 USPQ2d 1152, 1157 (Fed. Cir. 1988).

IV. Remand for Examination

The above noted reissue application and reexamination proceedings are merged. The reissue application and the reexamination file are being forwarded to the Director of Examining Group 3300 for examination in accordance with this decision.

Inquiries concerning this decision should be directed to the undersigned at (703)305-9285.



Lawrence E. Anderson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

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JUN 04 1997

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Baker, Maxham, Jester & Meador



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
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Washington, D.C. 20231

Paper No.19

TERRANCE A. MEADOR
BAKER, MAXHAM, JESTER & MEADOR
SYMPHONY TOWERS
750 "B" STREET, SUITE 3100
SAN DIEGO, CALIFORNIA 92101

In re Application of
Scott D. Augustine, et al.
Application No. 08/419,719
Filed: April 10, 1995
Attorney Docket No. 1342-119

COPY MAILED

JUN 02 1997

OFFICE OF
PATENT PUBLICATION

NOTICE

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MAY 03 2002

OFFICE OF PETITIONS

The purpose of this communication is to inform you that the above - identified application, which has received a patent number or an issue date, is being withdrawn from issue pursuant to 37 CFR 1.313.

The application is being withdrawn for the following purpose: to reopen prosecution. This withdrawal was requested by the Group Director. Any questions concerning this withdrawal should be addressed to the Group Director.

This application is being returned to the Office of the Director of Group 3300.

Telephone inquiries concerning this matter may be directed to the undersigned at (703) 308-5254.

Karna Cooper
Paralegal Specialist
Office of the Director
Office of Patent Publication

DOCKETED

JUN - 4 1997

FILE 942-119 *k*

The USPTO date stamp hereon will acknowledge receipt of:

ISSUE FEE for "Inflatable Lower Body Thermal Blanket"

The USPTO date stamp hereon will acknowledge receipt of:

SUE FEE for "Inflatable Lower Body Thermal Blanket"

Applicant: S.D. Augustine
Serial No.: 08/419,719
Filed: 4/10/95

Filed: March 4, 1997

or \$675.00

Classified: PTOL085B

Check # 17138 for \$675.00

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Publishing Division
MAR 07 1997

06

/cmr/jiv
2-119

17138

U.S.P.T.O.	Date	Description	Case	17138
000	03/03/97	1342-119 ISSUE FEE/COPIES	1342119	Amount 675.00

03/03/97 Total Paid 675.00

BAKER, MAXHAM, JESTER & MEADOR

A PROFESSIONAL LAW CORPORATION
SYMPHONY TOWERS (619) 233-9004
750 B STREET SUITE 3100 SAN DIEGO, CA 92101

PENINSULA BANK OF SAN DIEGO
SAN DIEGO, CA 92103
90-3482-1222

03/03/97 17138 *****\$675.00

DATE AMOUNT

SIX HUNDRED SEVENTY FIVE AND 00/100 DOLLARS

BY THE
DEALER

U.S.P.T.O.

GENERAL ACCOUNT

Terrence A. Mead

0017138 1222348221 820266401

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used when transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance order and notification of maintenance fees will be mailed to addresses entered in Block 1 unless you direct otherwise. (a) specifying a new correspondence address in Block 3 below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of issue fee or thereafter. See reverse for Certificate of Mailing, below.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Order Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending on the needs of the individual case. Any comments on the amount of time required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Issue Fee, Assistant Commissioner for Patents, Washington D.C. 20231

1. CORRESPONDENCE ADDRESS		2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)	
TERRANCE A MEADOR BAKER MAXHAM JESTER & MEADOR SYMPHONY TOWERS 750 B STREET SUITE 2770 SAN DIEGO CA 92101		INVENTOR'S NAME	
		Street Address	
		City, State and Zip Code	
		CO-INVENTOR'S NAME	
		Street Address	
		City, State and Zip Code	
		<input type="checkbox"/> Check if additional changes are enclosed	

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/419,719	04/10/95	010	GRAHAM, M	3304 02/03/97

First Named Applicant	AUGUSTINE.	SCOTT D.
-----------------------	------------	----------

FILE OF INVENTION INFLATABLE LOWER BODY THERMAL BLANKET

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPL. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 1342-119	607-107.000	J14	UTILITY	YES	\$645.00	05/05/97

Correspondence address change (Complete only if there is a change)

Terrance A. Meador, Esq.
BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, CA 92101

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR, alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.

- 1 BAKER, MAXHAM,
- 2 JESTER & MEADOR
- 3

ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE:
AUGUSTINE MEDICAL, INC.
(2) ADDRESS: (CITY & STATE OR COUNTRY)
Eden Prairie, Minnesota

☐ This application is NOT assigned.

☒ Assignment previously submitted to the Patent and Trademark Office.

☐ Assignment is being submitted under separate cover. Assignment should be directed to Box ASSIGNMENTS.

PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:

☒ Issue Fee ☒ Advance Order - # of Copies TEN (10)

6b. The following fees should be charged to:

DEPOSIT ACCOUNT NUMBER 02-0460

(ENCLOSE A COPY OF THIS FORM)

☐ Issue Fee ☐ Advance Order - # of Copies

☒ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Authorized Signature) *Terrance A. Meador* (Date) 3/4/97
TERRANCE A. MEADOR

NOTE: The Issue Fee will not be accepted from anyone other than the applicant, a registered attorney or agent, or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

Certificate of Mailing

ote: If this certificate of mailing is used, it can be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in

an envelope addressed to: Box ISSUE FEE
Assistant Commissioner for Patents
Washington, D.C. 20231

on: March 4, 1997 (Date)
TERRANCE A. MEADOR (Name of person making deposit)
Terrance A. Meador (Signature)
March 4, 1997 (Date)

The USPTO date stamp hereon will acknowledge receipt of:

FORMAL DRAWINGS for "Inflatable Lower Body Thermal Blanket"

Applicant: S.D. Augustine
Serial No.: 08/419,719
Filed: April 10, 1995

Mailed: March 3, 1997

Enclosed: FIVE (5) sheets of drawings

TAM/cmr/jiv
1342-119

The USPTO date stamp hereon will acknowledge receipt of:

FORMAL DRAWINGS for "Inflatable Lower Body Thermal Blanket"

Applicant: S.D. Augustine
Serial No.: 08/419,719
Filed: April 10, 1995

Mailed: March 3, 1997

Enclosed: FIVE (5) sheets of drawings

MAR 10 1997

TAM/cmr/jiv
1342-119

03



"PATENT"
IN AND UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
)
S.D. Augustine) Group No.: 3304
)
Serial No.: 08/419,719)
) Examiner:
) M. Graham
)
Filed: April 10, 1995) Batch No.: J14
)
For: INFLATABLE LOWER BODY THERMAL)
BLANKET)

Assistant Commissioner for Patents
Washington, D.C. 20231

ATTN: Draftsman

CERTIFICATE OF MAILING 37 C.F.R. 1.8
I hereby certify that this correspondence is being deposited with AND U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on AND date below:
<u>3/3/97</u> <u>Terrance A. Meador</u> Date

TRANSMITTAL OF FORMAL DRAWINGS

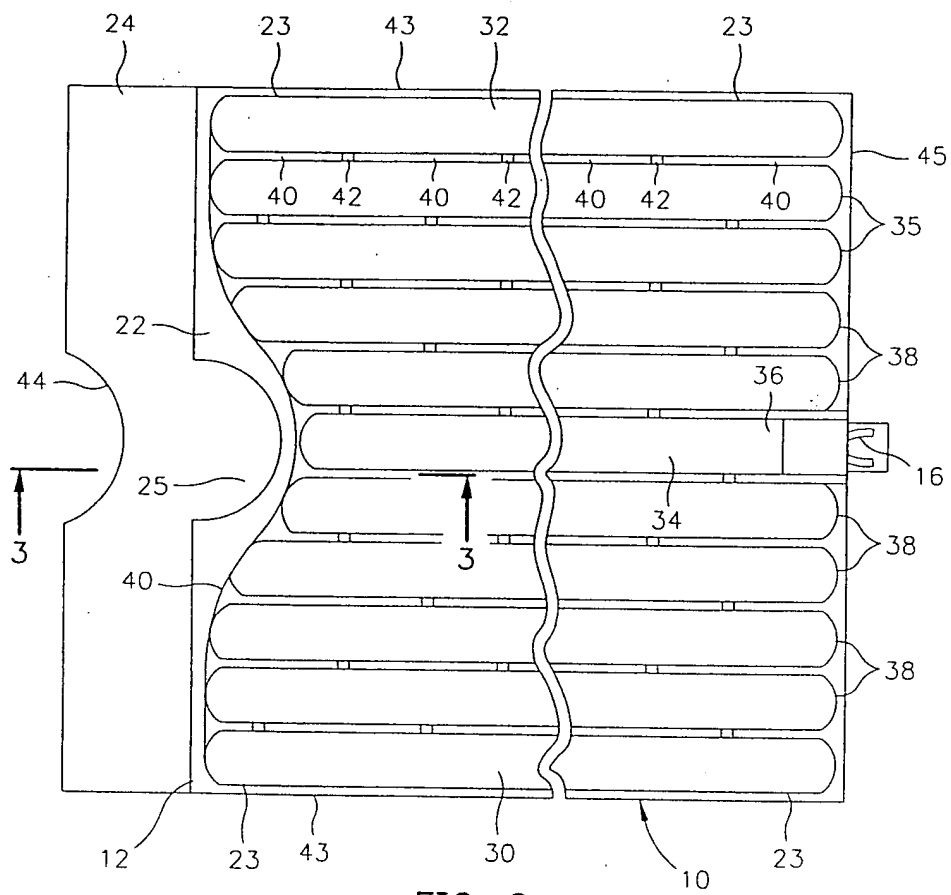
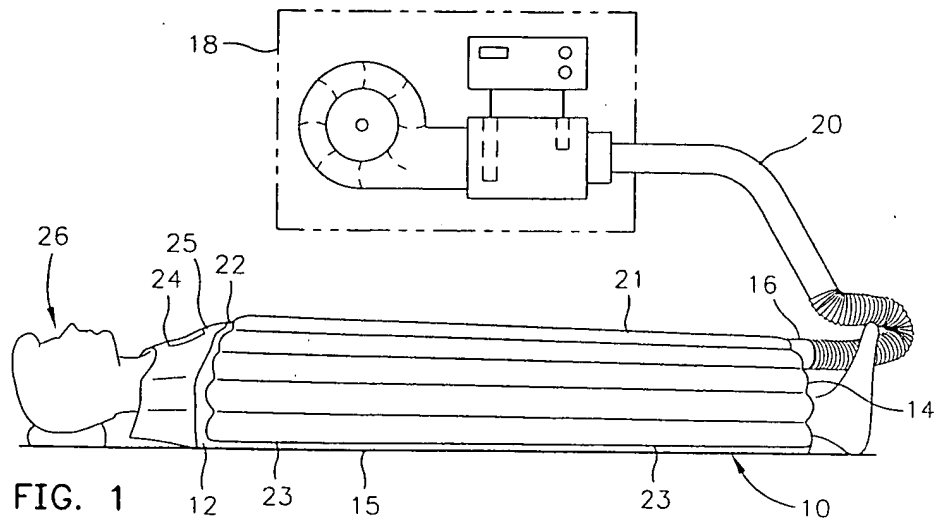
Transmitted herewith are FIVE (5) sheets of formal
drawings replacing informal drawings previously submitted.

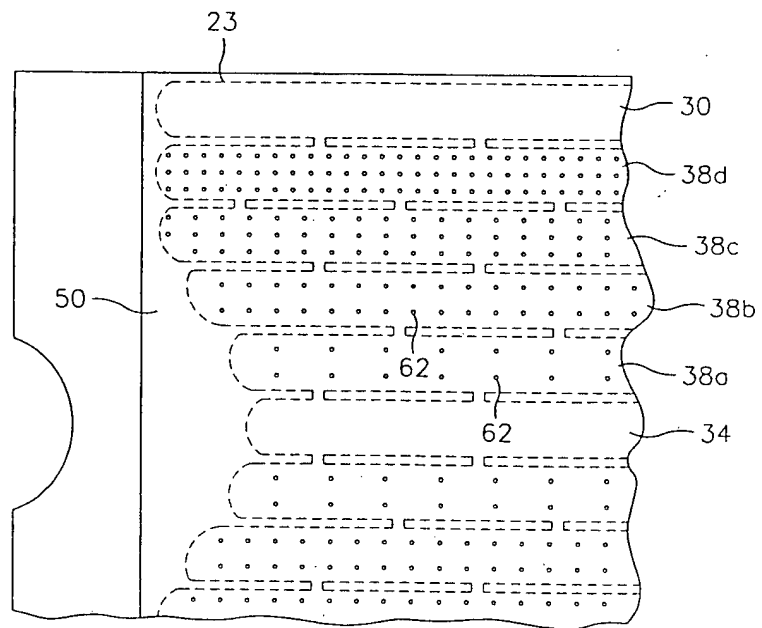
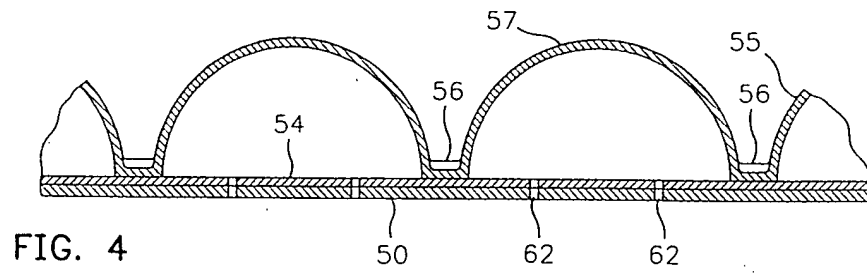
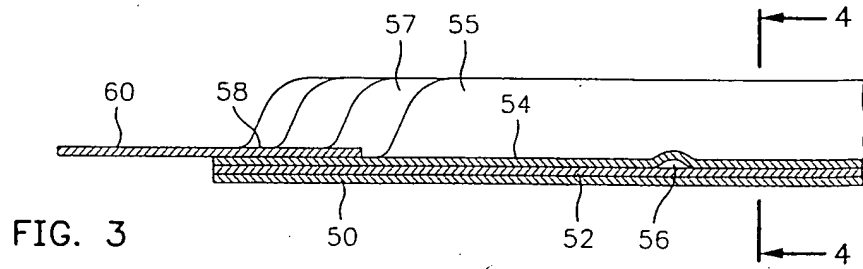
Respectfully submitted,

Terrance A. Meador

TERRANCE A. MEADOR
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101
Phone: 619/233-9004 Fax: 619/544-1246





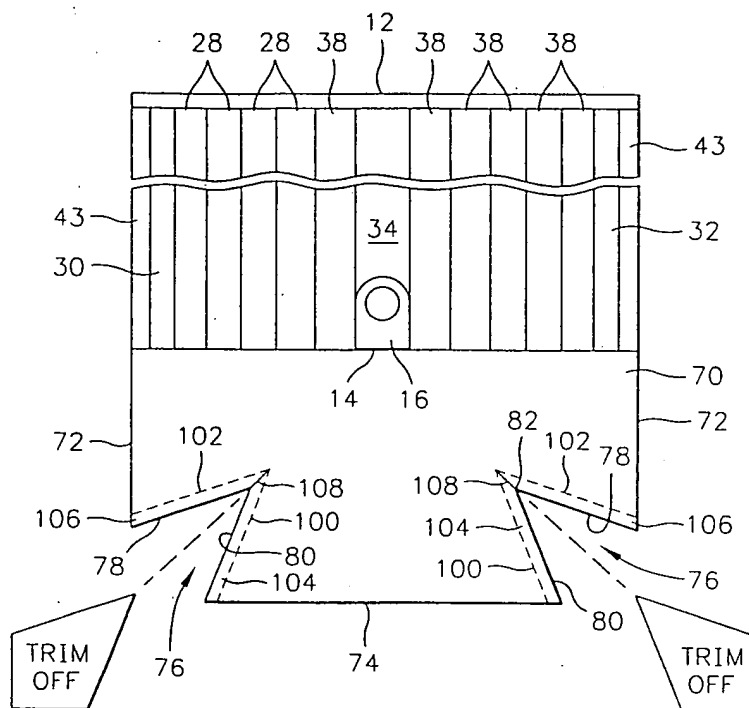


FIG. 6

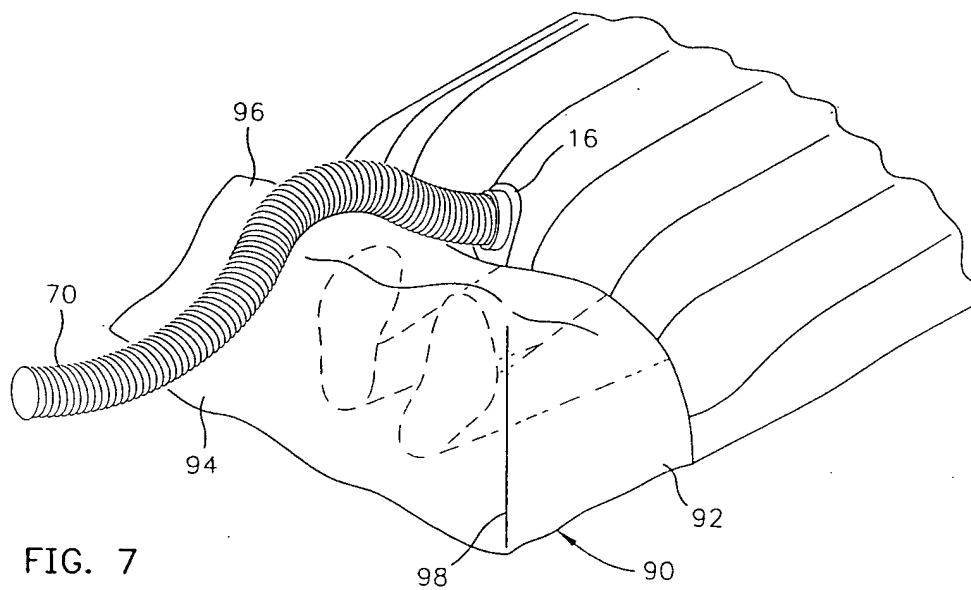


FIG. 7

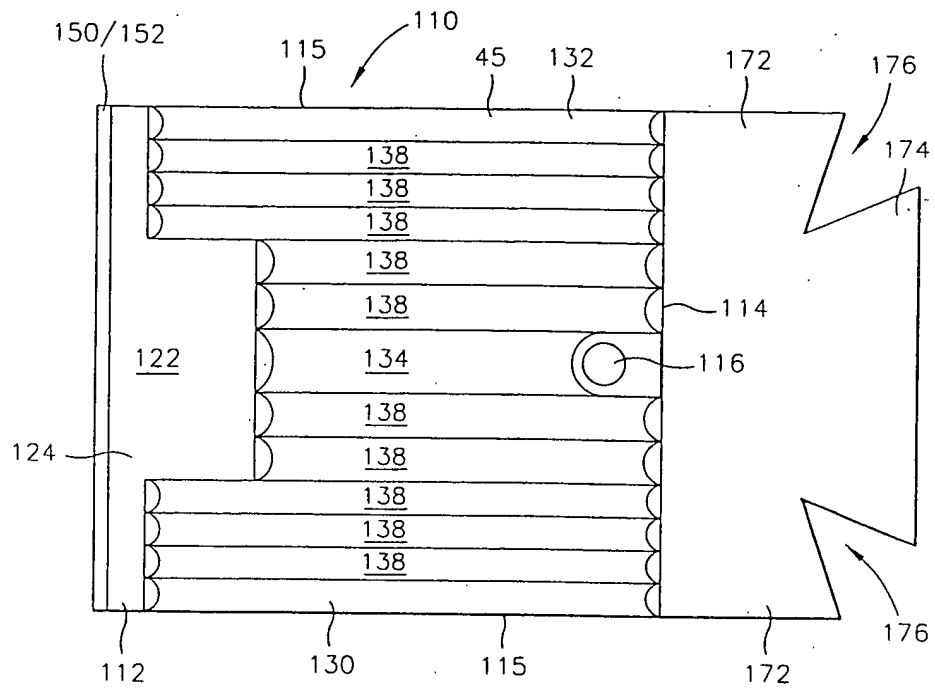


FIG. 8

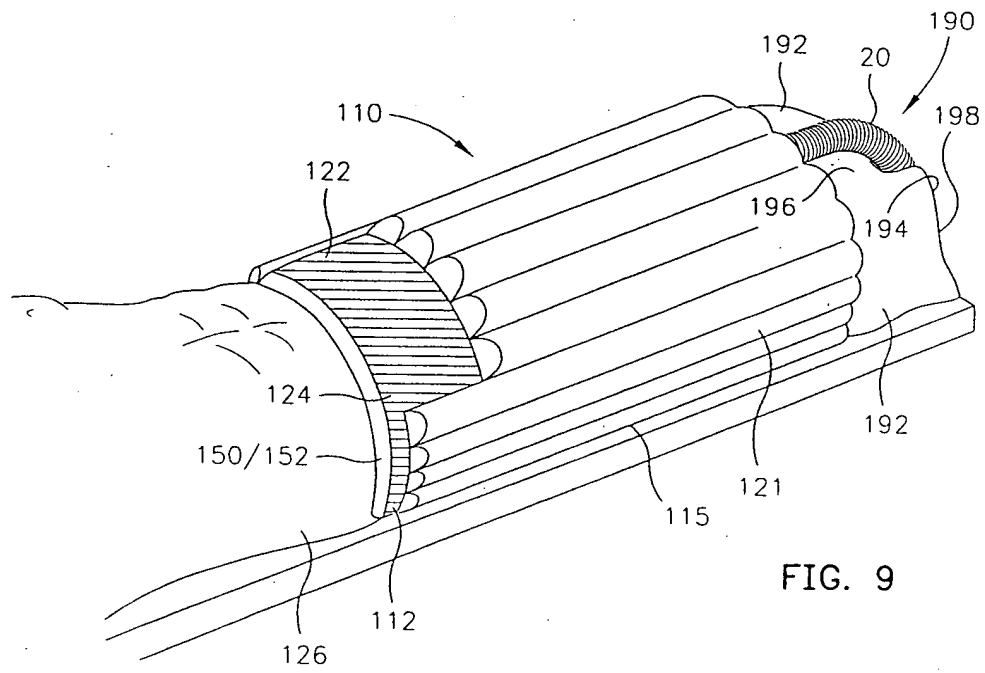


FIG. 9

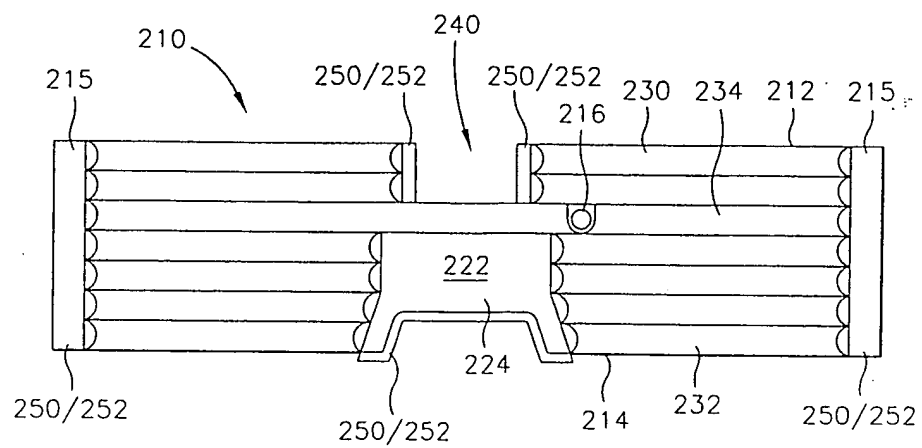


FIG. 10

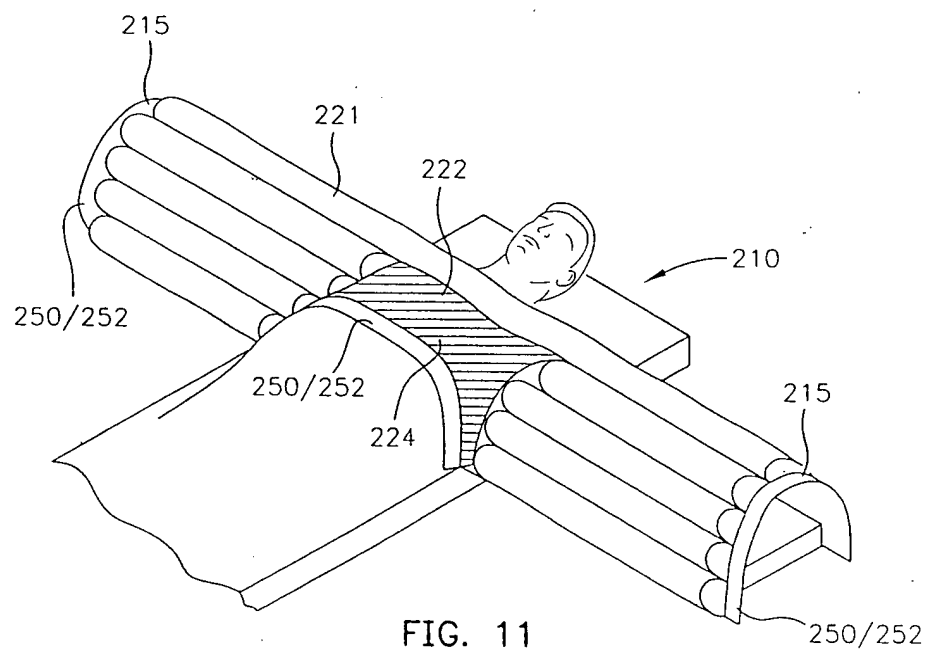


FIG. 11

The USPTO date stamp hereon acknowledges receipt of:

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97(d) for
"Inflatable Lower Body Thermal Blanket" (2 pgs.)

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995

Enclosures: Petition under 37 CFR 1.97(d)z (induplicate)
a check for \$130.00
PTO Form 1449 & One cited reference

Mailed: February 24, 1997

TAM/jiv
1342-119

The USPTO date stamp hereon acknowledges receipt of:

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97(d) for
"Inflatable Lower Body Thermal Blanket" (2 pgs.)

Applicant: S.D. Augustine et al 71480 U.S. PTO
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995



02/27/97

Enclosures: Petition under 37 CFR 1.97(d)z (induplicate)
a check for \$130.00
PTO Form 1449 & One cited reference

Mailed: February 24, 1997

TAM/jiv
1342-119

PT000
Vouch
10472

U.S.P.T.O.

Date Description

02/24/97 1342119 PETITION TO COMMISSION 1342119

17073
Amount
130.00

02/24/97 Total Paid 130.00

BAKER, MAXHAM, JESTER & MEADOR

A PROFESSIONAL LAW CORPORATION
SYMPHONY TOWERS (619) 233-9004
750 B STREET SUITE 3100 SAN DIEGO, CA 92101

PENINSULA BANK OF SAN DIEGO
SAN DIEGO, CA 92103
90-3482-1222

17073

Security features included. Details on back.

02/24/97 17073 *****\$130.00

DATE AMOUNT

ONE HUNDRED THIRTY AND 00/100 DOLLARS

PAY
TO THE
ORDER
OF
U.S.P.T.O.

GENERAL ACCOUNT

Turner A. Meador

⑈017073⑈ 1122234822⑈ 820266401⑈

"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
S.D. AUGUSTINE, ET AL.)	Group Art Unit: 3304
)	
Serial No.: 08/419,719)	
)	
Filed: April 10, 1995)	Examiner: M. Graham
)	
For: INFLATABLE LOWER BODY)	
THERMAL BLANKET)	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

CERTIFICATE OF MAILING	
37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:	
2/24/97 Date	<i>Tennant D. Head</i> Signature

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97(d)

In satisfaction of their continuing duty of candor and fair dealing, the applicants hereby cite the Order listed on the accompanying Form PTO-1449 with respect to the above-identified patent application under the provisions of 37 CFR, Sections 1.56, 1.97, and 1.98.

This application has been allowed by a Notice dated February 3, 1997. The Batch No. is O10. The issue fee has not been paid.

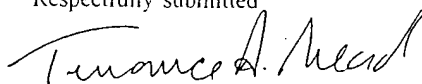
No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the statement.

A petition under 37 CFR 1.97(d)z accompanies this statement, as does a check for the fee specified in 37 CFR 1.17(I).

The Examiner is also requested to acknowledge the Information Disclosure Statement submitted on January 24, 1997.

The filing of this Information Disclosure Statement should not be construed to mean that a search was conducted in this application or that no other material information, as defined by 37 CFR 1.56, exists. The Examiner is respectfully requested to make the Order of record, if deemed relevant to the examination of this application.

Respectfully submitted



TERRANCE A. MEADOR
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

PHONE: 619/233-9004 FAX: 619/544-1246

Form PTO-1449

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**
(Use Several Sheets If Necessary)

Docket No. 1342-119

Application No. 08/419,719

Applicant: S.D. Augustine et al

Filing Date: 04/10/95

Group Art Unit 3304

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	ORDER by United States District Judge James M. Rosenbaum, <u>Augustine Medical, Inc., v. Mallinckrodt Group, Inc. and Mallinckrodt Medica, Inc.</u> , U.S. District Court, District of Minnesota, Fourth Division, Case No. 4-94-CV-875, January 28, 1997.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2/92 PTO)

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION
4-94-CV-875

Augustine Medical, Inc.

v.

Mallinckrodt Group, Inc. and
Mallinckrodt Medical, Inc.

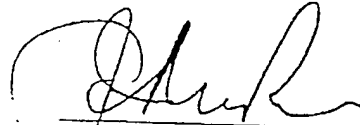
ORDER

Plaintiff objects to the Report and Recommendation, issued November 18, 1996, by the Honorable Franklin L. Noel, United States Chief Magistrate Judge. Plaintiff timely filed his objections to the Report, pursuant to Local Rule 72.1(c)(2).

Based upon a de novo review of the record herein, the Court adopts the Magistrate's Report and Recommendation. Accordingly, IT IS ORDERED that:

Defendant's motion for summary judgment of invalidity of claims 1, 3, 4, and 8 of the '371 patent is granted.

Dated: January 28th, 1997


JAMES M. ROSENBAUM
United States District Judge

112

FILED JAN 29 1997
CLERK
RECEIVED
JAN 29 1997

"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
S.D. AUGUSTINE, ET AL.)	Group Art Unit: 3304
)	
Serial No.: 08/419,719)	
)	
Filed: April 10, 1995)	Examiner: M. Graham
)	
For: INFLATABLE LOWER BODY)	
THERMAL BLANKET)	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

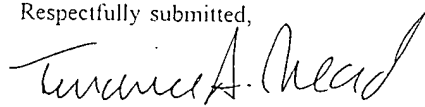
CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:	
2/24/97 Date	Financi A. Head Signature

PETITION UNDER 37 CFR 1.97(d)z

The Examiner is respectfully petitioned to consider and enter the accompanying
Information Disclosure Statement.

The petition fee set forth in 37 CFR 1.17(i) is satisfied by the accompanying check
in the amount of \$130. Authorization is hereby given to charge any deficiency to Deposit
Account No. 02-0460. This paper is submitted in duplicate.

Respectfully submitted,



TERRANCE A. MEADOR
Reg. No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 B Street, Suite 3100
San Diego, California 92101
Telephone (619) 233-9004

"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
S.D. AUGUSTINE, ET AL.)	Group Art Unit: 3304
)	
Serial No.: 08/419,719)	
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Filed: April 10, 1995)	Examiner: M. Graham
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For: INFLATABLE LOWER BODY)	
THERMAL BLANKET)	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

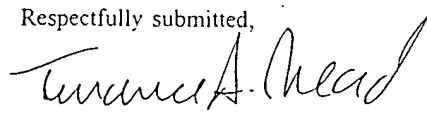
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in the amount of \$130. Authorization is hereby given to charge any deficiency to Deposit
Account No. 02-0460. This paper is submitted in duplicate.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Terrance A. Meador", written in a cursive style.

TERRANCE A. MEADOR
Reg. No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 B Street, Suite 3100
San Diego, California 92101
Telephone (619) 233-9004



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: Box ISSUE FEE
ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

RECEIVED

FEB 07 1997

Baker, Maxham, Jester & Meador

TERENCE A MEADOR
BAKER MAXHAM JESTER & MEADOR
SYMPHONY TOWERS
750 P STREET SUITE 2770
SAN DIEGO CA 92101

PGM1/0203

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/219,719	04/10/95	010	GRAHAM, M	03/04/97
First Named Applicant	ALBERTINE BLATT D.			

TITLE OF INVENTION
INFLATABLE LOWER BODY THERMAL BLANKET

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1542-119	007-107.000	014	UTILITY	YES	\$645.00	02/07/97

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.
PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS
APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

HOW TO RESPOND TO THIS NOTICE:

Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as yes, verify your
current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the
FEE DUE shown and notify the Patent and
Trademark Office of the change in status, or
B. If the status is the same, pay the FEE DUE shown
above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
B. File verified statement of Small Entity Status before, or with,
payment of 1/2 the FEE DUE shown above.

I. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE.
Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned.
If you are charging the ISSUE FEE to your deposit account, section "6b" of Part B should be completed.

II. All communications regarding this application must give application number and batch number.
Please direct all communication prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Patents Issuing on applications filed on or after Dec. 12, 1980 may require payment of
maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance
fees when due.**

PROCKETED
FEB 07 1997
1342-119

Notice of Allowability	Application No. 08/419,719	Applicant(s) Augustine et al.
	Examiner Mark S. Graham	Group Art Unit 3304

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to amendment B filed 11/4/96

☒ The allowed claim(s) is/are 26-35

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.
☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 3
☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.
☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152
☐ Interview Summary, PTO-413
☒ Examiner's Amendment/Comment
☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
☐ Examiner's Statement of Reasons for Allowance

ENT'D FEB 07 1997

POCKETED

Serial Number: 08/419,719

-2-


Art Unit: 3304

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In claim 28, line 2, "the" (first occurrence) has been replaced with --a-- to correct an antecedent basis problem.

Any inquiry concerning this communication should be directed to Mark S. Graham at telephone number (703) 308-1355.

MSG
23 January 1997


MARK S. GRAHAM
PRIMARY EXAMINER
GROUP 3300

The USPTO date stamp herein acknowledges receipt of:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT for "Thermal Blanket" (3 pgs.)

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995

Enclosures: PTO form 1449 & 10 cited references
a check for \$230.00

Mailed: *January 24, 1997*

TAM/jiv
1342-119

The USPTO date stamp hereon acknowledges receipt of:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT for "Thermal Blanket" (3 pgs.)

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995

Enclosures: PTO form 1449 & 10 cited references
a check for \$230.00

Mailed: *January 24, 1997*

TAM/jiv
1342-119



ER, MAXHAM, JESTER & MEADOR

16886

000 U.S.P.T.O.
ich Date Description
.74 01/24/97 1342119 IDS

Case
1342119

16886
Amount
230.00

01/24/97 Total Paid 230.00

BAKER, MAXHAM, JESTER & MEADOR
A PROFESSIONAL LAW CORPORATION
SYMPHONY TOWERS (619) 233-9004
750 B STREET SUITE 3100 SAN DIEGO, CA 92101

PENINSULA BANK OF SAN DIEGO
SAN DIEGO, CA 92103
90-3482-1222

16886

01/24/97 16886 *****\$230.00

DATE

AMOUNT

TWO HUNDRED THIRTY AND 00/100 DOLLARS

THE
IER

U.S.P.T.O.

GENERAL ACCOUNT

Terance A. Mead

⑈016886⑈ ⑆122234822⑆ 820266401⑈

"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
S.D. AUGUSTINE ET AL.) Group No. 3304
)
Serial No.: 08/419,719)
)
Filed: April 10, 1995) Examiner: S. Graham
)
For: THERMAL BLANKET)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

CERTIFICATE OF MAILING	
37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:	
1/24/97 Date	Tenacious A. Meade Signature

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In satisfaction of their duty of candor and fair dealing, the applicants hereby cite the documents listed on the accompanying Form PTO-1449 with respect to the above-identified patent application under the provisions of 37 CFR, 1.97(C) and 1.17(A). The filing of this Information Disclosure Statement should not be construed to mean that a search was conducted or that no other material information, as defined by 37 CFR 1.56, exists. The Examiner is respectfully requested to make of record this information if deemed relevant to the examination of this application.

In addition, disclosure is made of the following litigation matters in which U.S. Patent No. 5,405,371 is involved:

1. Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., Defendants, Civ. No. 4-94-CIV-875, U.S. District Court, District of Minnesota, Fourth Division;
2. Mallinckrodt Medical, Inc., Plaintiff v. Augustine Medical, Inc., Defendant, Civ. No. 4-95-CIV-1145 (formerly Case No. 4:95CV00514LOD), U.S. District Court, District of Minnesota, Fourth Division;
3. Augustine Medical, Inc., Plaintiff v. Gaymar Industries, Inc., Defendant, Civ. No. 4-94-CIV-888, U.S. District Court, District of Minnesota, Fourth Division;
4. Augustine Medical, Inc., Plaintiff v. Medisearch P.R., Inc., Baxter Healthcare Corporation, Baxter International Inc., and John K. Whitnev Sr., Defendants, Civ. No. 4-96-347, U.S. District Court, District of Minnesota, Fourth Division;
5. Augustine Medical, Inc., Plaintiff v. Progressive Dynamics, Inc., Eugene Kilbourn, Robert Crozier, Blue Ridge Anesthesia & Critical Care, Inc., Brett Smith, Steven Morris, Keomed, Inc., Desmond Keogh, Central Medical, Inc. and Dennis Mills, Defendants, Civ. No. 4-96-CV-345, U.S. District Court, District of Minnesota, Fourth Division;
6. Augustine Medical, Inc., Plaintiff, v. Respiratory Support Products, Inc., Smiths Industries, Inc. (USA), Smiths Industries Medical Systems and Smiths Industries PLC, Defendants, Civ. No. 4-96-CIV-346, U.S. District Court, District of Minnesota, Fourth Division;
7. Augustine Medical, Inc., Plaintiff v. Cincinnati Sub-Zero Products, Inc., Leonard D. Berke and Steven J. Berke, Defendants, Civ. No. 4-95-CIV-637, U.S. District Court, District of Minnesota, Fourth Division; and
8. Seabrook Medical Systems, Inc., Plaintiff, v. Augustine Medical, Inc., Defendant, Civ. No. C-1-95-1149, U.S. District Court, Southern District of Ohio, Western Division.

Matter No. 2 (Mallinckrodt v. Augustine) has been moved from the Eastern District of Missouri to the District of Minnesota, Fourth Division. Matters No. 2-7 have been consolidated with Matter No. 1 for discovery.

Document A, the Deposition of Randall C. Arnold (a coinventor of the '371 patent and this application), was taken in Matter No. 2, before consolidation with Matter No. 1. Documents B-E are exhibits in Document A.

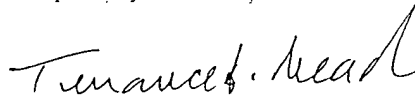
Document F, the defendant's memorandum for partial summary judgment in Matter No. 1, is referenced in the accompanying Statement by Attorney Under 37 CFR 1.175(b).

Document G, a report and recommendation by Magistrate Franklin L. Noel in Matter No. 1, includes findings to the effect that Claims 1, 3, 4 and 8 of the '371 patent are invalid under 35 U.S.C. 102(b). Documents H, I and J are memoranda related to Document G.

Activity that raised the issue discussed in Document G occurred at the Annual Meeting of the American Society of Anesthesiologists in October, 1989. This activity is described in Document A, beginning at page 85.

A check in the amount of \$230 is enclosed in accordance with § 1.97(c)) is enclosed. Please charge or credit Deposit Account 02-0460 any discrepancy. A duplicate of this paper is enclosed.

Respectfully submitted,



TERRANCE A. MEADOR
Attorney for Applicant(s)
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

Telephone: (619) 233-9004

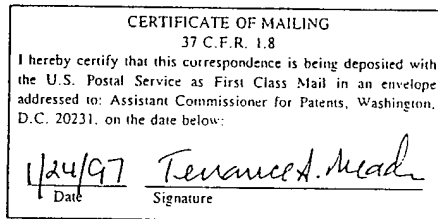
"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
S.D. AUGUSTINE ET AL.)	Group No. 3304
Serial No.: 08/419,719)	
Filed: April 10, 1995)	Examiner: S. Graham
For: THERMAL BLANKET)	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:



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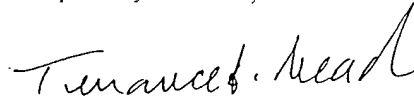
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Respectfully submitted,



TERRANCE A. MEADOR
Attorney for Applicant(s)
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

Telephone: (619) 233-9004

PTO-1449

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**

(Use Several Sheets If Necessary)

Docket No. 1342-119

Application No. 08/419,719

Applicant: S.D. Augustine et al

Filing Date: 04/10/95

Group Art Unit 3304

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	A	Deposition of Randall C. Arnold in <u>Mallinckrodt Medical, Inc. v. Augustine Medical, Inc.</u> , Case No. 4:95CV00514 LOD, Eastern District of Missouri, Eastern Division, February 27, 1996.
	B	Photograph Exhibit No. 1 of Deposition of Randall C. Arnold
	C	Photograph Exhibit No. 2 of Deposition of Randall C. Arnold
	D	Photograph Exhibit No. 3 of Deposition of Randall C. Arnold
	E	"Normothermia In The O.R.", Exhibit No. 4 of Deposition of Randall C. Arnold
	F	Memorandum In Support Of Defendant's Motion For Partial Summary Judgement Of Non-Infringement in <u>Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., Defendants</u> , Case No. 4:94-875; United States District Court, District of Minnesota, Fourth Division, pp. 19-25.
	G	Report and Recommendation of magistrate Judge Franklin L. Noel in <u>Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., Defendants</u> , Case No. 4:94-875, United States District Court, District of Minnesota, Fourth Division, pp. 1-19.
	H	Memorandum In Support of Defendants' Motion For Partial Summary Judgment, <u>Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., Defendants</u> , Case No. 4:94-CV-875, U.S. District Court, District of Minnesota, Fourth Division.
	I	Memorandum of Augustine Medical, Inc., <u>Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., Defendants</u> , Case No 4:94-CV-875, U.S. District Court, District of Minnesota, Fourth Division.
	J	Defendants' Reply To Memorandum Of Augustine Medical, Inc., <u>Augustine Medical, Inc., Plaintiff v. Mallinckrodt Group, Inc. and Mallinckrodt Medical, Inc., Defendants</u> , Case No 4:94-CV-875, U.S. District Court, District of Minnesota, Fourth Division.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2.92 PTO)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

Mallinckrodt Medical, Inc.,
Plaintiff,
vs.
Augustine Medical, Inc.,
Defendant.

The Videotape Deposition of RANDY ARNOLD,
taken pursuant to Notice of Taking Depositions, taken before
Jennifer A. Schaff, a Notary Public in and for the County of
Hennepin, State of Minnesota, taken on the 27th day of
February, 1996, at the law office of Briggs & Morgan,
2400 IDS Center, Minneapolis, Minnesota, commencing at
approximately 9:25 a.m.

VIDEO TECHNICIAN: This is the beginning
of the videotape record. My name is Alan Clapp, the
videotape operator for Sunshare Video, Minneapolis,
Minnesota. Today's date is February 27, 1996, the time is
approximately 9:28 a.m. Would the attorneys please introduce
themselves for voice identification?

MR. KURZ: My name is Ray Kurz with
Rothwell, Figg, Ernst & Kurz. We represent Mallinckrodt
Medical, Inc.

MS. SORIANO: Linda Soriano on behalf of
Augustine Medical.

VIDEO TECHNICIAN: The witness today is
Mr. Randy Arnold. Will the court reporter please swear in
the witness?

RANDY ARNOLD,
the Witness in the above-entitled matter
after having been first duly sworn,
deposes and says as follows:

VIDEO TECHNICIAN: Please proceed.

CROSS-EXAMINATION

BY MR. KURZ:

Q. Good morning, Mr. Arnold. You arrived at -
started working for Augustine in the summer of 1989, is that
correct?

1 APPEARANCES
2 RAYMOND A. KURZ, ESQUIRE, and CELINE M. RODRIGUEZ,
3 ESQUIRE, of the Law Firm of ROTHWELL, FIGG, ERNST & KURZ,
4 P.C., Columbia Square, 555 Third Street Northwest,
5 Washington, D.C., 20004, appeared for and on behalf of the
6 Plaintiff.

7 LINDA J. SORIANO, ESQUIRE, of the Law Firm of
8 OPPENHEIMER, WOLFF & DOWNHILL, P.A., Suite 1600, 100 South Seventh
9 Street, Suite 1400, Minneapolis, Minnesota 55402, appeared
10 for and on behalf of the Defendant.

11 ALSO PRESENT:
12 Alan Clapp, Video Technician
13 "The Signed Original is in the possession of Attorney Raymond
14 A. Kurz."

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16 Cross-Examination by Mr. Kurz . . . Page 1

17 ARNOLD DEPOSITION EXHIBITS MARKED
18 1, 2, 3 - Photographs . . . Page 38
19 1A, 2A, 3A - Transcripts of Photographs . . . Page 46
20 4 - "Herniaform in The O.R." Brochure . . . Page 49
21 4A - Transcripts of "Herniaform in The O.R."
22 Brochure . . . Page 56
23 5 - Hand-Drawn Diagram . . . Page 79
24 6 - Model 522 Upper Body Warming Blanket . . . Page 108
25 7 - Model 523 Lower Body Warming Blanket . . . Page 108
Exhibits 1 - 4 were retained by Attorney Soriano.
Exhibits 6 and 7 were retained by Attorney Kurz.

Page
1 A. It was more like the spring of '89, I believe
2 it was March or April.

3 Q. And when you first started working at
4 Augustine do you recall what your first - what your first
5 projects were?

6 A. I believe I spent the first month or so just
7 familiarizing myself with the product line and - and how it
8 was manufactured.

9 Q. Okay. After that did you start any
10 development work on any particular project?

11 A. I started work sometime in the summer of '89
12 on the - the O.R. line of products, warming units and
13 blankets.

14 Q. Prior to your start of work on the O.R. line
15 of warming units and blankets in the summer of 1989 to yo
16 knowledge had any work been done on that line before?

17 A. I don't believe so.

18 Q. Did you have discussions with anybody as to
19 how to go about designing an O.R. line of blankets and
20 blowers?

21 A. Dr. Augustine, I believe.

22 Q. Anyone else?

23 A. I don't recall.

24 Q. Do you recall what Dr. Augustine told you?

25 A. With regards to?

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1 Q. With regards to designing the O.R. line of
2 products. Did he give you parameters or guidance in any way?
3 A. I believe he did.
4 Q. Do you recall what that was?
5 A. A basic description I think he gave me of the
6 operating room layout and how our product would need to
7 interface with -- with patients.
8 Q. Do you recall what he told you about the basic
9 description of the O.R. room layout?
10 A. We talked about operating room tables, gas
11 machines where they're placed, other types of equipment that
12 might be present in the O.R.
13 Q. Did he show you any pictures or photographs?
14 A. Yes.
15 Q. Did you actually visit any hospital O.R. rooms
16 to acquaint yourself with the layout?
17 A. I don't recall.
18 Q. But you do recall seeing pictures?
19 A. Yes.
20 Q. Do you recall whether Dr. Augustine pointed
21 out that it would be favorable to have a -- strike that. Do
22 you recall any discussions regarding which side of the
23 operating room table would be a more appropriate side for the
24 blower to be placed?
25 A. Yes.

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1 Q. And this is during the summer of 1989?
2 A. I believe so.
3 Q. What was your discussions in that regard?
4 A. I believe Dr. Augustine told me that the --
5 the gas machine was typically placed on the
6 anesthesiologist's right side and that that side was
7 generally quite cluttered with equipment. And we felt that
8 -- or he felt that the -- probably the best place to put our
9 piece of equipment would be on the -- on the left-hand side.
10 Q. Is there -- did you go -- did you, in fact, go
11 about designing the O.R. blankets with the thought in mind
12 that the equipment would be placed on the left side?
13 A. I think we -- we left it open.
14 Q. That wasn't a consideration at all in your
15 design, in your design work?
16 A. We certainly had discussions about it.
17 Q. Did you decide to do anything with respect to
18 the design of the blanket in view of those discussions that
19 the right side of the operating room table was cluttered?
20 A. Well, we discussed which side we should put
21 the -- the -- the entrance card on for our blanket.
22 Q. And this is in the summer of 1989?
23 A. Yes.
24 Q. And what was your discussions about which side
25 to put the entrance card on?

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1 A. Dr. Augustine, I think, seemed to feel that in
2 a majority of cases that the anesthesiologist would probably
3 end up using a -- a card on the left-hand side, but that
4 there might be certain instances where a clinician would
5 prefer putting the -- the hose and the machine on the
6 right-hand side.
7 Q. What instances would those be, did you discuss
8 that?
9 A. I guess just a preference for, you know, how
10 cluttered the O.R. was and whether there was room for
11 additional equipment on the left side.
12 Q. Did you discuss the advisability of having a
13 single nozzle entry versus two nozzle entries?
14 A. I'm sure we did.
15 Q. Do you recall what you discussed in that
16 regard?
17 A. Not particularly, no.
18 Q. How about generally? Do you remember any
19 general -- anything general about any discussions that you've
20 had with Dr. Augustine during the summer of 1989 regarding
21 one nozzle entry versus two nozzle entries?
22 A. Not specifically, no, I don't.
23 Q. Did you retain the photographs that you looked
24 at or pictures that you looked at regarding the O.R. room
25 layout?

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1 A. I don't believe so.
2 Q. Did you keep a file of your early design work
3 in 1989?
4 A. I did not.
5 Q. Did you during that development process of the
6 summer of 1989 did you make any drawings or notes?
7 A. I'm sure I did.
8 Q. What did you do with the drawings and notes?
9 A. Probably threw them away long ago.
10 Q. Do you recall throwing them away?
11 A. Not specifically.
12 Q. Did you look for those drawings and notes in
13 connection with production of documents in connection with
14 the lawsuits?
15 A. Yes.
16 Q. And were you able to find any?
17 A. No.
18 Q. Did you sketch any pictures of an O.R. room
19 layout yourself?
20 A. I couldn't say for certain.
21 Q. Did Dr. Augustine sketch any pictures of an
22 O.R. room layout?
23 A. I don't recall.
24 Q. You indicated that you had discussions about
25 how your product would interface with patients. Do you

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1 recall what those discussions were?

2 A. I believe we talked about some of the - the
3 primary positions that - that patients were in for varying
4 types of surgeries and how the - we thought that our - our
5 product might interface with - with the patient and the
6 surgeon.

7 Q. What do you mean by how your product would
8 interface with the patient and the surgeon?

9 A. Well, we were trying to basically pioneer a -
10 a - a new product and come in with something that hadn't
11 been done before. And we - we didn't want to place a piece
12 of equipment or a product on the patient or in the way of the
13 surgeon that would give them a negative first impression of
14 our product. So we were somewhat concerned with designing a
15 - a system which would effectively warm the patient but not
16 interfere with - with the other goings on of - of the
17 operating room.

18 Q. Prior to the summer of 1989 you didn't have
19 any experience with respect to designing products for the
20 medical profession did you?

21 A. I don't believe so.

22 Q. When you say you were pioneering a new
23 product something that hadn't been done before, what were
24 you referring to?

25 A. Convectively warming patients

1 intraoperatively.

2 Q. Were you familiar with any other methods of
3 warming patients other than convective warming with respect
4 to the operating room?

5 A. Water mattress technology.

6 Q. Anything else?

7 A. Not that I can recall.

8 Q. When did you first become aware of water
9 mattress technology?

10 A. When I started working with Augustine Medical.

11 Q. How did you learn about water mattress
12 technology while working at Augustine Medical?

13 A. Through discussions probably with
14 Dr. Augustine and looking at literature.

15 Q. You mentioned that you discussed the primary
16 position patients were in for varying types of surgeries.

17 What types of positions did you discuss?

18 A. We discussed positions where or situations
19 where we thought that we could let's say interface with our
20 product effectively and be able to - to warm the patient.
21 So we talked about like your basic abdominal cases where -
22 or upper chest cases where we wouldn't have a lot of space
23 and might be able to use either a, you know, a lower body
24 blanket to - to warm the feet or legs or be able to position
25 the patient with their arms outstretched on armboards and be

1 able to gain enough surface area there to effectively
2 maintain normothermia.

3 Q. Did Dr. Augustine show you photographs or
4 illustrations of these various types of positions that
5 patients would be in for surgery?

6 A. I believe he did.

7 Q. And again, what were the specific types of
8 positions that patients were in for surgery that you
9 discussed?

10 MS. SORANNO: Objection, asked and
11 answered.

12 BY MR. KURZ:

13 Q. Well, the first thing you said was abdominal
14 cases. Do you recall saying abdominal cases a few minutes
15 ago?

16 A. I recall that.

17 Q. In abdominal cases do you recall how - the
18 position that Dr. Augustine showed you patients were in for
19 abdominal cases?

20 A. I don't recall specifically, no.

21 Q. How about upper chest cases, do you recall
22 what position Dr. Augustine showed you patients were in for
23 upper chest cases?

24 A. I don't specifically recall, no.

25 Q. But you recall that patients - do you recall

1 seeing pictures of patients with their arms outstretched on
2 an armboard?

3 A. I believe so.

4 Q. Do you recall seeing any pictures where
5 patients were lying with their arms next to their bodies?

6 A. I believe so.

7 Q. Was there a decision during the summer of '89
8 to attempt to design a convective warming blanket that would
9 warm patients when they were in surgery with their arms
10 stretched out on armboards?

11 A. Can you repeat that question?

12 MR. KURZ: Could you read it back, please?
13 (Whereupon, at this time the requested
14 portion of the record was read back by
15 the Court Reporter.)

16 A. I believe so.

17 BY MR. KURZ:

18 Q. Was there a decision during the summer of 1989
19 to attempt to design a convective warming blanket to warm
20 patients when their arms were next to their bodies as opposed
21 to stretched out?

22 A. I believe so.

23 Q. And what was the blanket design that -
24 generally that was decided upon in that second instance?

25 A. The lower body surgical blanket.

1 Q. Were there any other basic blanket designs
2 that were decided to be developed during the summer of '89
3 aside from the arms stretched out upper body and the lower
4 body?

5 A. I think we decided that we could -- if we had
6 those two blankets for those two situations we could
7 basically have enough of a product line to launch.

8 Q. Were any other designs discussed?

9 A. I don't recall.

10 Q. Do you recall discussing a arms to the side
11 upper body blanket design?

12 A. I don't recall.

13 Q. Did anyone work with you during the summer of
14 1989 to develop these blanket designs?

15 A. I believe I had some help.

16 Q. Who helped you?

17 A. I don't recall for certain.

18 Q. Who was in the -- what was your title at that
19 time?

20 A. I don't know that I had a title.

21 Q. What did you think you were?

22 A. I was the -- outside of Dr. Augustine I was
23 the -- the R & D employee.

24 Q. Were there any other R & D employees?

25 A. Scott's dad and -- and another fellow named

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1 Dave Sorvig worked to build manufacturing machinery for us in
2 an R & D capacity.

3 Q. Did Dave Sorvig work on blanket design at all?

4 A. I don't believe so.

5 Q. Did Scott's dad work on blanket design?

6 A. I believe he helped me from time to time.

7 Q. Did he help you during the summer of 1989?

8 A. I don't recall.

9 Q. Can you think of who else might have helped
10 you during the summer of 1989 aside from Scott's dad?

11 A. Dr. Augustine himself.

12 Q. Anyone else?

13 A. Are you talking about the specific design or
14 are you talking about, you know, just working on fabricating
15 blankets?

16 Q. Working on fabricating blankets.

17 A. I probably had some help from line workers
18 within the plant to build prototypes.

19 Q. Do you recall any of their names?

20 A. I don't.

21 Q. Did anyone else work on blanket design?

22 A. I don't recall.

23 Q. How often would you meet with Scott Augustine
24 during the summer of '89 to work on blanket design?

25 A. I don't recall specifically.

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1 Q. Do you recall approximately? Would it be once
2 a day, once a week, once a month?

3 A. I'm not for certain. I think he could have
4 still been residing in Kansas City at that time and, I think,
5 coming up to the Twin Cities like every other week or
6 something, I'm not for certain. I know at that time, you
7 know, if I had a question I would track him down.

8 Q. Were you primarily responsible with coming up
9 with prototypes of different blanket designs to meet the
10 desire to create an upper body blanket to cover a patient
11 with their arms stretched out?

12 A. I believe so.

13 Q. And you would come up with prototypes and then
14 show them to Dr. Augustine?

15 A. Yes.

16 Q. And you came up with the basic design layout
17 of a upper body blanket to cover a patient with their arms
18 stretched out?

19 A. Dr. Augustine and I, yes.

20 Q. Together?

21 A. Yes.

22 Q. Do you recall who came up with the first
23 sketch of a blanket of that type?

24 A. I do not.

25 Q. Do you recall whether there was a sketch prior

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1 to building prototypes?

2 A. I don't recall.

3 Q. Do you recall what the first prototype looked
4 like for use in connection with a patient with their arms
5 stretched out?

6 A. I do not.

7 Q. Even a rough idea of what it looked like?

8 A. I couldn't say for certain.

9 Q. Do you recall whether anyone in marketing had
10 any input in to the design of the O.R. blankets?

11 A. I don't recall.

12 Q. How about sales, do you recall meeting or
13 discussing O.R. blanket designs with anyone from sales at
14 Augustine?

15 MS. SORANNO: Is this still the summer of
16 '89?

17 MR. KURZ: The summer of '89.

18 A. I don't recall.

19 BY MR. KURZ:

20 Q. Do you recall how long it took you from the
21 time you started the project to the development of the first
22 prototype?

23 A. I don't, no.

24 Q. Approximately how long, a day, a week, a
25 month?

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1 A. Things happened really fast. I would guess a
2 day or two probably.
3 Q. Do you recall how many prototypes you made
4 during the summer of - approximately how many prototypes you
5 made during the summer of 1989 in connection with the
6 development of the O.R. blankets?
7 A. I do not.
8 Q. Would it have been closer to ten or closer to
9 a hundred?
10 A. It would be closer to a hundred.
11 Q. What did you do with the prototypes that you
12 had come up with? Did you store them someplace?
13 A. Initially for a time I think we probably did.
14 Q. Where did you store them?
15 A. In my work area.
16 Q. Do you know what happened to those prototypes?
17 A. Probably thrown out.
18 Q. Do you know that they were thrown out?
19 A. I would guess so. I haven't seen them in
20 years.
21 Q. Have you looked for them?
22 A. No. I've cleaned out the R & D area and moved
23 a number of times and I've never seen them, so I would guess
24 that they're nowhere - nowhere around.
25 Q. I'm sorry?

1 A. I would guess that they're nowhere around.
2 Q. Have you undertaken a search for them?
3 A. Not specifically, no.
4 Q. With respect to the lower body O.R. blanket do
5 you recall how the basic shape was determined, how you
6 decided on a basic shape?
7 A. I believe we were looking for a blanket to
8 cover the lower extremities of the patient, and we felt that
9 a - a slight variation on our full body PACU blanket would
10 suffice in this situation.
11 Q. Did you look at any designs of surgical drapes
12 to assist in your consideration of appropriate shapes for
13 lower body blanket designs?
14 A. I don't recall.
15 Q. Do you ever recall seeing any drawings or
16 pictures of surgical drapes?
17 A. I remember discussing draping procedures.
18 Q. With Dr. Augustine?
19 A. Yes.
20 Q. During the summer of 1989?
21 A. Yes.
22 Q. Do you recall what you discussed with respect
23 to draping procedures?
24 A. I do not.
25 Q. How did you arrive at the basic shape of the

1 upper body design?
2 A. Through discussions with Dr. Augustine and
3 looking at our existing blankets and our technology and
4 ability to produce blankets and started prototyping blankets.
5 I guess.
6 Q. Do you remember what the early prototypes
7 looked like? Could you sketch out for me what your first
8 prototype that you remember looked like?
9 A. I just don't recall.
10 Q. Do you recall considering the - strike that
11 Do you recall looking at the design of surgical drapes with
12 respect to the - your design of the upper body arms
13 stretched out blanket?
14 A. I remember discussing draping procedures. I
15 don't know if we looked at particular designs.
16 Q. Do you recall considering - do you recall
17 considering whether there should be cut-out portions at the
18 head and abdomen in your upper body blanket during the summer
19 of 1989?
20 A. I'm certain that we did at some point.
21 Q. At some point did you decide that it would be
22 appropriate to include cut-out portions around the neck and
23 abdomen?
24 A. I believe so.
25 Q. And why did you determine that it was

1 appropriate to include a cut-out portion for the - for the
2 neck?
3 A. Dr. Augustine and I discussed the
4 anesthesiologist's needs in terms of monitoring the patient
5 and the ability to monitor breathing circuits and - and
6 other equipment, and felt that we needed unobscured or at
7 least visually to be able to see the patient at all times.
8 So rather than covering their head with a - a blanket,
9 though it might have warmed the patient very well, it would
10 have obscured the anesthesiologist's view.
11 Q. Anything else?
12 A. Not that I recall.
13 Q. How about the cut-out portion for the abdomen,
14 do you recall why you thought it was appropriate to include
15 cut-out portion for the abdomen?
16 A. It's to keep the blanket out of the surgical
17 field, to give a means for adhering the blanket to the - to
18 the patient, and preventing the migration of air into the
19 surgical field.
20 Q. That's what the cut-out portion did?
21 A. Well, that's what's occurring at that portion
22 on the blanket where it attaches. I mean, the cut-out
23 portion also facilitates the - the extremities of that
24 particular blanket to drape down and tuck along the - the
25 armboards.

1 Q. Does the neck cut-out portion also facilitate
2 that draping and attachment to the armboards?
3 A. Yes.
4 Q. If you didn't have the cut-out portions the
5 blanket would bunch up and wouldn't conform to the body of
6 the patient, isn't that right?
7 MS. SORANNO: Objection, calls for
8 speculation.
9 A. I couldn't say.
10 BY MR. KURZ:
11 Q. Wasn't that one of the considerations though,
12 that it would lie evenly on the patient and wouldn't bunch
13 up?
14 A. I'm not sure I follow your question.
15 Q. What did you mean when you said that it
16 facilitated draping and -- and adhering to the armboards?
17 A. It's narrower in the portion where it crosses
18 the -- the patient and then it's wider on -- on either end,
19 and those portions are able to tuck around the armboard. If
20 it was full width the whole way it would have -- on the one
21 side it would protrude down in to the surgical field, it
22 would cover up the -- the patient's head and -- and prohibit
23 the -- the anesthesiologist from monitoring the patient's
24 vital signs.
25 Q. Did -- did any of your design work include

1 design of the nozzle entrance openings on the blankets?
2 A. I believe so.
3 Q. When you arrived at Augustine, Augustine
4 blankets had a nozzle entrance that they used in connection
5 with the PACU blankets, isn't that right?
6 A. Yes, they did.
7 Q. Did you redesign that nozzle entrance in
8 connection with the O.R. blankets?
9 A. I don't recall.
10 Q. What work do you recall doing on nozzle
11 entrances during the summer of '89?
12 A. Just in regards to the blankets we were
13 working on developing I think we just talked about placement
14 and -- and where they belonged and whether there should be
15 one or two on the upper body cover.
16 Q. Did you consider whether there should be one
17 or two on the lower body cover?
18 A. I don't recall.
19 Q. Do you recall doing any design work on the
20 entrance itself on the design of the cardboard portion?
21 A. In what time period?
22 Q. In the summer of '89.
23 A. I don't believe so.
24 Q. Did you do any work on how the cardboard
25 portion of the entrance, nozzle entrance would be adhered to

1 the blanket in the summer of '89?
2 A. I don't recall.
3 Q. Do you recall the results of any discussions
4 with surgeons as to -- do you recall seeing any results of
5 any discussions with surgeons as to the appropriate place to
6 put the nozzle entrance on the upper body blanket?
7 A. I don't recall.
8 Q. Do you recall arriving at what we'll call a
9 finalized prototype of an upper and lower body blanket during
10 the summer of 1989?
11 A. I would guess it probably stretched more into
12 the fall of '89.
13 Q. Do you know how far into the fall?
14 A. I couldn't say for sure.
15 Q. During the fall of -- either the summer or the
16 fall of '89 did you do any work on redesigning the nozzle
17 entrance itself?
18 A. I don't recall.
19 Q. To your knowledge is the nozzle entrance that
20 was incorporated into the finalized prototypes of the upper
21 and lower body blankets the same?
22 A. I'm not following your question.
23 Q. Was the nozzle in the finalized prototypes of
24 the upper and lower body blankets that you completed in the
25 fall of 1989 was the basic design of the nozzle entrance in

1 those two blankets the same?
2 A. I believe so.
3 Q. Was that design essentially the same as the
4 PACU blankets that had previously been sold?
5 A. I believe so.
6 Q. And can you -- can you sketch out for me what
7 that nozzle design looked like?
8 MS. SORANNO: What time frame?
9 MR. KURZ: The one that was incorporated
10 in the finalized prototypes in the fall of 1989, which the
11 witness testified were the same as the previous PACU
12 blankets.
13 THE WITNESS: He's talking about the card
14 that goes on the --
15 MR. KURZ: That's correct.
16 MS. SORANNO: Counsel, when you say
17 "prototype" what do you mean?
18 MR. KURZ: Well, if you have an objection,
19 make it. The witness understood what I was talking about.
20 BY MR. KURZ:
21 Q. Do you understand what I said when I said
22 finalized prototypes? What did you have in your mind when
23 you answered my questions with respect to finalized
24 prototypes?
25 A. Basically the design we came up in prototyping

1 and were ready to release to the market.
 2 Q. And that was in the fall of 1989, right?
 3 A. I believe so.
 4 MR. KURZ: Off the record.
 5 VIDEO TECHNICIAN: Going off video record.
 6 (Whereupon, a brief off the record
 7 discussion was held.)
 8 (Whereupon, a brief recess was taken
 9 from 10:05 to 10:15.)
 10 VIDEO TECHNICIAN: Continuing with video
 11 record.
 12 BY MR. KURZ:
 13 Q. We had been discussing the design of the
 14 nozzle entrance in the finalized prototype of the upper and
 15 lower body blankets that existed in the fall of 1989. And
 16 yesterday during Mr. Anderson's deposition he sketched out
 17 the basic form of a nozzle entrance that existed when -- when
 18 he was -- when he came to Augustine in 1990, and I'll show
 19 you that, and that was marked as Anderson Exhibit 5
 20 yesterday. Do you see that?
 21 A. Uh-hum.
 22 Q. Is that the same basic shape of nozzle
 23 entrance that -- that you were referring to with respect to
 24 the finalized prototype that existed in the fall of 1989?
 25 A. I believe so.

1 Q. And can you tell me how that was -- how that
 2 was constructed? What was it -- what were the materials, how
 3 was it -- who manufactured it and how it was manufactured,
 4 et cetera?
 5 MS. SORANNO: Objection, lack of
 6 foundation.
 7 A. I believe it was just a heavy weight cardboard
 8 substrate with a adhesive backing and a post-off liner on --
 9 on one side.
 10 BY MR. KURZ:
 11 Q. When you say post-off liner that would be on
 12 the back side?
 13 A. On the back side.
 14 Q. Were these -- what would you refer to this as,
 15 the hose card? What do you feel comfortable calling that?
 16 A. We used to call them flags.
 17 Q. Flags? Do you understand what I would be
 18 talking about if I said a hose card?
 19 A. Yes.
 20 Q. But you referred to them as flags?
 21 A. Flags or hose cards.
 22 Q. Were these manufactured during -- up through
 23 the fall of 1989 were these flags or hose cards manufactured
 24 for Augustine by an outside vendor?
 25 A. I believe so.

1 Q. Do you know who that vendor was?
 2 A. I do not.
 3 Q. Do you know who manufactures the hose cards
 4 for Augustine today?
 5 A. I do not.
 6 Q. Have you ever known the identity of any hose
 7 card manufacturer for Augustine?
 8 A. At some point I guess I probably have, but
 9 I've forgotten.
 10 Q. Do you know if Augustine has changed
 11 manufacturers of hose cards?
 12 A. I couldn't say for certain.
 13 Q. When these hose cards -- when these hose cards
 14 arrived from the manufacturer, I'm talking about the hose
 15 cards that existed up through the fall of 1989, did they come
 16 with the hole cut out in the center as is shown in Anderson
 17 Exhibit 5?
 18 A. I don't recall.
 19 Q. The hose cards that you worked with in
 20 connection with your prototypes that you worked on during the
 21 summer through the fall of 1989, when you were working on
 22 those prototypes did you adhere the hose card to the -- to
 23 the blankets?
 24 A. Probably.
 25 Q. You peeled off the back and then adhered them

1 to locations on the -- on the blankets?
 2 A. Probably.
 3 Q. Do you recall whether the hole was already cut
 4 out when you were -- when you were doing that?
 5 A. Before adhering them?
 6 Q. Yes.
 7 A. I don't think so, no.
 8 Q. You don't think the hole was cut out?
 9 A. No.
 10 Q. The PACU blankets that were in existence when
 11 you came to the -- to Augustine in 1989 do you recall those
 12 blankets?
 13 A. To a degree, yes.
 14 Q. When those were shipped to customers was the
 15 hole in the hose card already cut out, the cardboard, was the
 16 cardboard removed from the hole?
 17 MS. SORANNO: Objection, lack of
 18 foundation.
 19 A. I don't recall.
 20 BY MR. KURZ:
 21 Q. Do you recall when -- when the completed
 22 blankets were put in packages whether there was cardboard in
 23 this hole of the -- of the nozzle entrance?
 24 MS. SORANNO: Objection, lack of
 25 foundation.

1 A. I just don't recall.
 2 BY MR. KURZ:
 3 Q. And just for the record, my references to --
 4 to "this" have been to Anderson Exhibit 5, do you understand
 5 that?
 6 A. Yes.
 7 Q. And that's -- was discussed by Mr. Anderson as
 8 the hose card that was in existence when he arrived at
 9 Augustine. The -- do you recall whether in connection with
 10 the PACU blankets that were being sold during the summer and
 11 up through the fall of 1989 whether those blankets -- strike
 12 that. Do you recall whether the PACU blankets that were
 13 being sold during the summer and fall of '89 included a hose
 14 card where the blanket material under the hose card had been
 15 cut in any way?
 16 MS. SORANNO: Objection, lack of
 17 foundation.
 18 BY MR. KURZ:
 19 Q. And when I say -- when I refer to the blanket
 20 material under the hose card I mean in this entrance way, the
 21 circular entrance way, was that cut?
 22 A. I don't recall.
 23 Q. So you don't recall whether it was sold with
 24 the -- with plastic covering the entrance way, or whether it
 25 was sold with the plastic cut away, is that right?

1 MS. SORANNO: same objection.
 2 A. I just don't recall.
 3 BY MR. KURZ:
 4 Q. Now, when you adhered these hose cards to the
 5 blankets that you were working on during the summer and fall
 6 of 1989 how did you hook up the hose to the blanket?
 7 A. Push the hose nozzle in through the card.
 8 Q. Did you have to break -- how did you break the
 9 plastic?
 10 A. Sometimes the hose end itself would do it.
 11 sometimes you would just poke your finger through it. The
 12 plastic was very thin.
 13 Q. So you wouldn't have to cut the plastic to do
 14 that?
 15 A. No, not necessarily.
 16 Q. Do you recall taking a knife ever and cutting
 17 the plastic with a knife?
 18 A. I might have.
 19 Q. But you also recall just poking the hose
 20 directly through the hose card through the plastic without
 21 cutting it?
 22 A. I believe so, yes.
 23 Q. And when you poked the hose through do you
 24 recall whether there was cardboard that you were also pushing
 25 through?

1 A. I don't believe so.
 2 Q. So it's now your recollection that there was
 3 no cardboard in this round inner circle portion of the hose
 4 card when you adhered them to the blankets, is that right?
 5 A. When I was making prototypes, yes.
 6 Q. Do you recall whether you removed any
 7 cardboard from this inner circle or whether they were -- they
 8 came that way from the manufacturer?
 9 MS. SORANNO: Objection, asked and
 10 answered.
 11 A. I just don't recall.
 12 BY MR. KURZ:
 13 Q. Was it difficult -- did you experience any
 14 problems with inserting the hose into the prototypes through
 15 the hose card when you did not punch the plastic through with
 16 your finger or a knife but rather had the hose punch through
 17 the plastic?
 18 A. I don't recall.
 19 Q. You don't recall ever having a problem?
 20 A. I just don't remember.
 21 Q. Do you remember designing any way to
 22 facilitate a customer -- strike that. When you arrived at
 23 the finalized prototype how was the hose entrance designed to
 24 be utilized by the customer?
 25 A. I don't recall specifically.

1 Q. Do you recall ever designing any means for
 2 facilitating a customer inserting the hose into the hose card
 3 and into the blanket?
 4 A. I'm not sure I follow that question.
 5 Q. Do you recall any design considerations that
 6 went in to your design of the nozzle entrance that would
 7 facilitate the customer putting the nozzle into the blanket?
 8 A. I don't recall.
 9 Q. Do you recall any discussions you had with
 10 Scott Augustine or anyone else with respect to facilitating
 11 customers pushing the nozzle into the blanket?
 12 A. I don't recall.
 13 Q. Did there, in fact, come a time in the fall of
 14 1989 when you felt that you had arrived at a design of an
 15 upper body blanket that was ready for manufacture?
 16 A. I believe so.
 17 Q. Would the same be true of a lower body O.R.
 18 blanket?
 19 A. Yes.
 20 Q. Do you recall when in the fall of 1989?
 21 A. I do not.
 22 Q. Did you attend the New Orleans A.S.A. in 1989?
 23 A. I did.
 24 Q. How many -- strike that. Do you attend the
 25 A.S.A. shows every year?

1 A. For the most part, yes.
 2 Q. Was that the first one that you ever attended?
 3 A. I believe so.
 4 Q. Was it your objective to -- strike that. Did
 5 you have an understanding as to whether you had completed a
 6 upper body blanket design that was ready for production at
 7 the time of the A.S.A. show in 1989?
 8 A. I believe so.
 9 Q. Is there any doubt in your mind?
 10 A. No.
 11 Q. Are you certain that the -- strike that. How
 12 about a lower body blanket, as of the A.S.A. show in 1989 had
 13 you completed a design of a lower body blanket that you
 14 believed was ready for production?
 15 A. I believe so.
 16 Q. And what do you understand me to mean when I
 17 say "production"?
 18 A. Well, we were there at the show introducing
 19 product and we were taking orders and ready to fill the
 20 customers' needs.
 21 Q. When I say "ready for production" I mean mass
 22 produce and distribute to customers. Does that change your
 23 answer at all?
 24 A. No.
 25 Q. When I say "does that change your answer" does

1 that change your answer with respect to whether you had a
 2 product that was available for production -- that was ready
 3 for production in the fall of 1989 with respect to the upper
 4 and lower body blankets?
 5 A. I'm not sure I follow you.
 6 Q. That was not a very articulate question. Let
 7 me try it again. Based on how I've just defined production
 8 and available for production, is it your answer that as of
 9 the A.S.A. show in 1989 you had completed a design of the
 10 upper body blanket that was ready for production?
 11 MS. SORANNO: Objection, asked and
 12 answered.
 13 A. Yes.
 14 BY MR. KURZ:
 15 Q. Same with the lower body design?
 16 MS. SORANNO: Asked and answered.
 17 A. Yes.
 18 BY MR. KURZ:
 19 Q. Was that the designs that were -- were those
 20 designs the designs that were shown at the 1989 show?
 21 A. I believe so.
 22 Q. Did those designs, in fact, ever go in to
 23 production?
 24 A. I believe so.
 25 Q. And when I say "those designs" I mean designs

1 that had two parts?
 2 A. I believe so.
 3 Q. Do you know how many were produced?
 4 A. I do not.
 5 Q. Do you know approximately how many were
 6 produced?
 7 A. I couldn't tell you.
 8 Q. Was it more than ten?
 9 MS. SORANNO: Objection, lack of
 10 foundation.
 11 A. I'm certain, yea.
 12 BY MR. KURZ:
 13 Q. You're certain it was more than ten?
 14 A. Yea.
 15 Q. Was it more than a hundred?
 16 MS. SORANNO: Same objection.
 17 A. I couldn't say.
 18 BY MR. KURZ:
 19 Q. Was it more than 50?
 20 MS. SORANNO: Same objection.
 21 A. I really don't know.
 22 BY MR. KURZ:
 23 Q. So you know it was more than 10 but you're not
 24 sure it was more than 50, is that right?
 25 A. I just wouldn't be willing to speculate beyond

1 that.
 2 MR. KURZ: Could I have the original
 3 photographs, please?
 4 BY MR. KURZ:
 5 Q. I'm going to hand you three photographs and
 6 ask whether you've ever seen these before?
 7 A. I believe so.
 8 Q. When did you first see these photographs?
 9 A. I couldn't say for certain.
 10 Q. Was it more than a year ago?
 11 A. I don't recall.
 12 Q. Was it more than two weeks ago?
 13 A. I don't recall.
 14 Q. You don't know whether the first time you saw
 15 these photographs was more than two weeks ago?
 16 A. I just don't recall.
 17 Q. It could have been within the last two weeks
 18 that you first saw these photographs?
 19 A. I just don't recall.
 20 Q. Was it within the past week?
 21 A. I don't remember. I just don't remember. I
 22 have seen the pictures before, I just don't know when it was
 23 Q. You don't know whether it was within -- within
 24 the past week was the first time you ever saw these
 25 photographs?

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1 MS. SORANNO: Objection, asked and
2 answered.
3 A. That's what I've said basically, yes.
4 BY MR. KURZ:
5 Q. Do you know whether the first time you saw
6 these photographs was within the last three days?
7 A. I don't know.
8 Q. Do you know whether the first time you saw
9 these photographs was yesterday?
10 A. I don't think I saw them yesterday. I know I
11 didn't see them yesterday.
12 Q. How about the day before yesterday?
13 A. I didn't see them then either.
14 Q. Okay. But three days ago you're not sure?
15 A. Well, three days ago was Saturday, I didn't
16 see them then either.
17 MR. KURZ: Why don't we have a discussion
18 off the record.
19 VIDEO TECHNICIAN: Going off video record.
20 (Whereupon, a brief off the record
21 discussion was held.)
22 VIDEO TECHNICIAN: Returning to video
23 record.
24 MR. KURZ: I'd like to mark these
25 photographs as exhibits, please.

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1 (Whereupon, ARNOLD deposition Exhibit
2 Numbers 1 - 3 were marked for identification
3 by the court reporter.)
4 MR. KURZ: Why don't we go off the record
5 again a second.
6 VIDEO TECHNICIAN: Going off video record.
7 (Whereupon, a brief off the record
8 discussion was held.)
9 VIDEO TECHNICIAN: Continuing with video
10 record.
11 BY MR. KURZ:
12 Q. I've just had these three photographs marked
13 as deposition exhibits and we've marked them Exhibits 1, 2, 3
14 of your deposition of today's date. We've had this one with
15 the gentleman standing in the picture as Exhibit Number 1.
16 this one with a picture of a woman off to the left as
17 Exhibit 2, and this one with a woman slightly more towards
18 the center as Exhibit Number 3. Do you recall ever seeing
19 these photographs that have been marked as exhibits other
20 than with your counsel present?
21 A. I don't recall.
22 Q. Do you recall seeing them with your counsel
23 present?
24 A. I believe so.
25 Q. Do you know what these - do you recognize

1 what these are pictures of independent of anything that your
2 counsel has told you?
3 A. Well, that's our trade show booth in
4 New Orleans.
5 Q. And you know that by looking at these?
6 A. Well, I built the booth, so.
7 Q. And this is the 1989 trade show in
8 New Orleans?
9 A. Yes.
10 Q. And can you identify the blanket that's - the
11 two blankets that are shown in Exhibit Number 1? Why don't
12 you start with the one on the left and then go to the one on
13 the right, if you can.
14 A. The one on the left is the lower body O.R.
15 surgical blanket and the one on the right is the upper body
16 O.R. surgical blanket.
17 Q. Would these be the blankets that we've
18 referred to as finalized prototypes earlier?
19 A. They were the same design as - as the
20 prototypes.
21 Q. And do you know whether looking at the blanket
22 on the right, the upper body blanket I think you identified
23 that as?
24 A. Yes.
25 Q. Do you know how many blankets of that design

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1 with two ports were produced by Augustine?
2 MS. SORANNO: Objection, asked and
3 answered.
4 A. I do not.
5 BY MR. KURZ:
6 Q. Do you know if it was more than ten?
7 MS. SORANNO: Asked and answered.
8 A. I'm certain it was.
9 BY MR. KURZ:
10 Q. Do you know if it was more than 50?
11 MS. SORANNO: Asked and answered.
12 A. Probably.
13 BY MR. KURZ:
14 Q. Okay, that's a little bit different answer
15 than when I was asking you before about how many dual port
16 upper body blankets were produced you said you didn't
17 remember when I asked you if it was 50. Do you now have a
18 recollection that it was more than 50?
19 MS. SORANNO: Objection, asked and
20 answered.
21 A. I just don't recall.
22 BY MR. KURZ:
23 Q. So you're not sure whether it was more than
24 50?
25 MS. SORANNO: Asked and answered.

1 A. I don't recall.
 2 BY MR. KURZ:
 3 Q. How about the lower body blanket do you know
 4 how many -- which is shown on the left, you identified that
 5 as the blanket on the left of Exhibit I, do you know how many
 6 lower body blankets of the design pictured in Exhibit I were
 7 produced?
 8 A. I do not.
 9 Q. Do you know if it was more than ten?
 10 A. I would guess so.
 11 Q. Do you know if it was more than 50?
 12 A. Probably.
 13 Q. Do you know if it was more than a hundred?
 14 A. I'm pretty certain it would be, yes.
 15 Q. Do you know how many of the upper body blanket
 16 that is shown in Exhibit I were actually sold?
 17 A. I do not.
 18 Q. Do you know if any were ever sold?
 19 MS. SORANNO: objection, lack of
 20 foundation.
 21 A. I don't know.
 22 BY MR. KURZ:
 23 Q. You don't know if any were ever sold?
 24 A. I don't work in the sales department.
 25 Q. Do you know if any were ever distributed to

1 Q. How do you know it was changed?
 2 A. I just seem to have a recollection of it.
 3 Q. But you don't -- you never -- this is a
 4 recollection notwithstanding the fact that you didn't see it
 5 being changed and didn't change it yourself?
 6 A. Well, certainly every day I would guess at the
 7 start of the show that fresh product was put out there.
 8 Q. You said you would guess, but you don't know
 9 that do you?
 10 A. I don't know that, no.
 11 Q. Was someone in charge of setting up the
 12 product for the show every day?
 13 A. I don't know specifically. I know I had a
 14 hand in setting the -- the show up every day.
 15 Q. But you don't recall whether you set up the
 16 fresh product every day do you?
 17 A. I don't recall specifically, no.
 18 Q. Who else had a hand in setting up the product
 19 every day?
 20 A. The people working the booth.
 21 Q. Who else worked the '89 booth?
 22 A. Doug Augustine, Sue Dykins, Scott Augustine, I
 23 just don't recall beyond that.
 24 Q. Do you know whether Bob Vosskuhler was at this
 25 show?

1 customers?
 2 MS. SORANNO: objection, lack of
 3 foundation.
 4 A. I don't know.
 5 BY MR. KURZ:
 6 Q. Do you know if any were ever utilized in
 7 clinical trials?
 8 A. I don't know.
 9 Q. How do you know more than ten were produced?
 10 A. It was just typical that when we went to trade
 11 shows that we had ample product on hand. And with customers
 12 poking at them and looking at the product that we wanted to
 13 keep our product fresh and -- and looking good, so we changed
 14 our -- our product -- our display product on a regular basis.
 15 Q. How often did you change the display -- the
 16 upper body product during the course of the 1989 show?
 17 A. I couldn't say.
 18 Q. Do you know if it was more than twice?
 19 A. Oh, I'm certain.
 20 Q. Was it more than five times?
 21 A. I couldn't say.
 22 Q. Did you change the product?
 23 A. I don't recall.
 24 Q. Did you see it being changed?
 25 A. I just don't recall.

1 A. I don't recall.
 2 Q. Do you recall when Bob Vosskuhler began
 3 working at Augustine?
 4 A. I do not.
 5 Q. Was it after 1989?
 6 MS. SORANNO: objection, lack of
 7 foundation.
 8 A. I don't recall.
 9 BY MR. KURZ:
 10 Q. Do you recall how many lower body blankets you
 11 had at the -- at the '89 show?
 12 A. I do not.
 13 Q. Do you know whether you had more than one?
 14 A. I would assume so.
 15 Q. But you don't know?
 16 A. I don't know.
 17 Q. But you do know that you had more than one
 18 upper body blanket or you don't know that either?
 19 MS. SORANNO: objection, asked and
 20 answered.
 21 A. I'm just assuming that we would have had.
 22 BY MR. KURZ:
 23 Q. But you don't know? You don't know whether
 24 you had more than one upper body blanket at the show do you?
 25 MS. SORANNO: objection, asked and

1 answered.
 2 A. I don't recall.
 3 BY MR. KURZ:
 4 Q. Do you see the blower unit shown in Exhibit I,
 5 blower units shown in Exhibit I?
 6 A. I do.
 7 Q. Did you work on the design of those blower
 8 units?
 9 A. I did.
 10 Q. Are the units shown in Exhibit I prototypes or
 11 production models?
 12 A. They were the first machines off the
 13 production.
 14 Q. Do you know whether any orders were taken for
 15 the blower units during the 1989 show?
 16 A. I don't know.
 17 Q. Do you know whether any orders were taken for
 18 the lower body blankets during the '89 show?
 19 A. I don't know that either.
 20 Q. Do you know whether any orders were taken for
 21 the upper body blankets during the '89 show?
 22 A. I don't know that.
 23 Q. Was the lower body blanket that's shown in
 24 Exhibit I a production model or a prototype?
 25 A. A production model, I believe.

1 Q. How do you know that?
 2 A. That was our -- our final design and I believe
 3 we were producing them.
 4 Q. You say you were producing them?
 5 A. I believe so.
 6 Q. But you don't know whether you produced more
 7 than ten?
 8 A. I do not.
 9 Q. How about the upper body blanket was that a
 10 production model -- the upper body blanket that's shown in
 11 Arnold Exhibit I is that a prototype or a production model?
 12 A. It's a production model, I believe.
 13 Q. How do you know that?
 14 A. I don't, I just believe that it was.
 15 Q. But you have no basis for that statement?
 16 A. It's -- it's the design that -- that we went
 17 to production with.
 18 Q. Is the -- the design that's shown -- the
 19 blanket that's shown as the lower body blanket in Exhibit I
 20 that's a design that was eventually sold to customers wasn't
 21 it?
 22 MS. SORANNO: Objection, lack of
 23 foundation.
 24 A. I believe so, but I don't know.
 25 BY MR. KURZ:

1 Q. Can you think of any differences between the
 2 lower body blankets that were sold -- strike that. Do you
 3 know when the first lower body O.R. blankets were first sold?
 4 A. I do not.
 5 Q. You do know that there -- do you have an
 6 understanding that there came a point in time when lower body
 7 O.R. blankets were first sold to customers?
 8 A. Well, I would assume so, yes.
 9 Q. And you have an awareness of -- of the first
 10 type of O.R. lower body blanket that was sold to customers
 11 don't you?
 12 A. I believe so, yes.
 13 Q. Is that the same design that's shown in
 14 Exhibit I?
 15 A. I believe so.
 16 Q. Are you aware of any changes that were made at
 17 all to the lower body blanket from the design that was shown
 18 at the '89 show versus the design that was ultimately sold to
 19 customers?
 20 A. I don't know for certain.
 21 Q. Do you know when the first -- do you know
 22 approximately when the first blower units of the type shown
 23 in Exhibit I were sold to customers?
 24 MS. SORANNO: Objection, lack of
 25 foundation.

1 A. I do not.
 2 BY MR. KURZ:
 3 Q. Do you know what year it was in?
 4 MS. SORANNO: Same objection.
 5 A. I do not.
 6 BY MR. KURZ:
 7 Q. Do you know what year the first lower body
 8 O.R. blankets were sold?
 9 MS. SORANNO: Same objection.
 10 A. I do not.
 11 MR. KURZ: What objection is that,
 12 counsel?
 13 MS. SORANNO: Foundation.
 14 BY MR. KURZ:
 15 Q. Do you know what year the first upper body
 16 blankets were sold to customers?
 17 MS. SORANNO: Same objection.
 18 A. I do not.
 19 MR. KURZ: Could I have the original
 20 brochure, please?
 21 BY MR. KURZ:
 22 Q. Do you know whether there were any changes as
 23 between the design of the upper body blanket that's shown in
 24 Exhibit I versus the design that was ultimately sold to
 25 customers?

1 A. I don't know.
 2 Q. Do you know whether Augustine ever sold a dual
 3 port upper body blanket to customers?
 4 A. I don't know.
 5 Q. Do you know whether Augustine ever sold a
 6 single port upper body blanket to customers?
 7 A. I'm certain we have.
 8 MR. KURZ: Counsel, I'm going to need to
 9 mark this as an exhibit as well.
 10 MS. SORANNO: That's fine, but let's
 11 decide where we're going to put the exhibit stamp.
 12 MR. KURZ: What if we put it right here?
 13 MS. SORANNO: That's fine. Again, I'm
 14 going to retain the original.
 15 MR. KURZ: Okay. If you could make me a
 16 nice color photocopy of this as well during the break I would
 17 appreciate it.
 18 MS. SORANNO: I will.
 19 MR. KURZ: Okay, I would like to have this
 20 marked as the next deposition exhibit, please. And this is
 21 the "Normothermia In The O.R." brochure.
 22 (Whereupon, ARNOLD Deposition Exhibit
 23 Number 4 was marked for identification
 24 by the court reporter.)
 25 BY MR. KURZ:

1 Q. Have you ever seen the brochure that's been
 2 marked as exhibit -- Arnold Exhibit 4?
 3 A. Yes, I have.
 4 Q. Do you recall when you first saw that
 5 brochure?
 6 A. I don't.
 7 Q. Do you know whether you first saw that
 8 brochure more than a year ago?
 9 A. I believe so.
 10 Q. Do you know if you saw it more -- first saw
 11 that brochure more than three years ago?
 12 A. I just don't recall.
 13 Q. Do you know whether you've seen this brochure
 14 other than with counsel?
 15 A. I believe so.
 16 Q. You indicated you don't know whether you've
 17 seen this brochure more than three years ago, is that right?
 18 A. Yes.
 19 Q. So you don't recall whether you saw this
 20 brochure at the '89 trade show do you?
 21 A. I just don't recall.
 22 Q. And you have no recollection of distributing
 23 this brochure at the '89 trade show do you?
 24 A. I don't recall, no.
 25 Q. Do you know approximately when this brochure

1 was produced?
 2 A. I do not.
 3 Q. Do you know the year?
 4 A. I do not.
 5 Q. Do you know where this photograph came from
 6 that's on the front of the brochure?
 7 A. I do not.
 8 Q. Do you know who's responsible within Augustin
 9 for preparing the brochure?
 10 A. I do not.
 11 Q. Who was working in the marketing department in
 12 1989?
 13 A. I don't recall.
 14 Q. Have you ever seen this photograph that's
 15 shown on the cover of the brochure anywhere else but in t
 16 brochure?
 17 A. I don't recall.
 18 Q. Do you know whether the blanket that's shown
 19 in this brochure, either on the cover or on the inside of the
 20 brochure, is the same blanket design that's shown in
 21 Exhibit 1 on the right-hand side?
 22 A. It appears to be, but I couldn't say for sure.
 23 Q. Did you ever demonstrate the -- the use of the
 24 blanket at the '89 show?
 25 A. What do you mean by demonstrate?

1 Q. Inflate it and show it to people who were at
 2 the show?
 3 A. I believe I was there describing it to people
 4 that came up.
 5 Q. While it was inflated?
 6 A. While it was inflated.
 7 Q. Do you have a recollection as to whether with
 8 respect to the blanket that's shown in -- in Exhibit 1
 9 whether -- you see there's a hose connected to one side of
 10 the blanket?
 11 A. Yes.
 12 Q. Is there another hose connection shown in that
 13 photograph of the upper body blanket?
 14 A. There appears to be on the side over there.
 15 Q. Do you know whether that hose connection
 16 remained sealed as of the time this was photographed?
 17 A. It appears to be, otherwise I would guess the
 18 blanket would be deflated.
 19 Q. Do you recall when you were describing the
 20 blanket while it was inflated at the show whether the --
 21 whether one hose opening remained sealed?
 22 A. I don't recall.
 23 Q. Do you recall whether there was any scoring or
 24 perforations to the plastic within the hose card on the
 25 blankets that were shown at the 1989 trade show?

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1 A. I don't recall.
 2 Q. And when I say "within the hose card" I mean
 3 within the round circular portion of the hose card.
 4 A. That's what I took you to mean, yes.
 5 Q. Did you attend the trade -- do you know how
 6 many days the 1989 trade show was?
 7 A. I don't recall.
 8 Q. Did you attend it every day that it was --
 9 that Augustine had a booth?
 10 A. I don't recall.
 11 Q. Did you attend it more than one day?
 12 A. I believe so.
 13 Q. Do you know how -- when you attended it what
 14 did you do at the show?
 15 A. I set up the booth before the trade show
 16 began, helped with getting the exhibits out in the morning,
 17 and spent some time talking with customers who came by who
 18 were interested in our product and I spent some time taking
 19 in the rest of the trade show exhibits.
 20 Q. Do you know where you spent most of your time
 21 during the trade show? Was it at the Augustine booth would
 22 you say?
 23 A. I don't recall.
 24 Q. Do you recall ever designing the entrance
 25 opening -- strike that. Do you recall ever designing the

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1 plastic that would appear within the circle of the hose card
 2 on the upper body blanket to be scored or perforated?
 3 A. I don't recall.
 4 Q. Do you recall seeing the plastic that was in
 5 that hose card -- strike that. Do you recall ever seeing any
 6 plastic within the circular portion of the hose card being
 7 scored or perforated?
 8 A. I don't recall. Could I take a break for just
 9 a minute and go to the restroom?
 10 Q. Sure.
 11 VIDEO TECHNICIAN: Going off video record.
 12 (Whereupon, a brief recess was taken
 13 from 11:05 to 11:15.)
 14 VIDEO TECHNICIAN: Continuing with video
 15 record.
 16 BY MR. KURZ:
 17 Q. With respect to the blanket that -- the upper
 18 body blanket that was shown at the -- at the 1989 trade show,
 19 how was -- how was it intended for users to insert the hose?
 20 How was the blanket constructed such that users would insert
 21 the hose?
 22 A. I don't recall.
 23 Q. You designed the blanket didn't you?
 24 A. Yes.
 25 Q. And you don't recall how you designed the

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1 blankets so that users would insert the hose?
 2 A. Well, that I understood that they would stick
 3 the hose nozzle in to the -- in to the card.
 4 Q. In to the -- in to the --
 5 A. The hose card, the flag.
 6 Q. In to the area of the hose card that does not
 7 -- that does not have cardboard in it, is that your
 8 understanding?
 9 A. The area meant for insertion, yes.
 10 Q. And was it intended that they would just break
 11 the plastic by shoving the hose in?
 12 A. I don't recall.
 13 Q. How about the lower body blanket do you recall
 14 whether the plastic that was within the -- well, I'll call it
 15 the cut-out region of the hose card, the round circular
 16 cut-out region, do you recall whether that was pre-cut or
 17 whether it was intended that the user would insert the hose
 18 and break the plastic?
 19 A. As I recall there was a small X, a score done
 20 with a sharp knife or.
 21 Q. Was it actually -- did the score go all the
 22 way through? Was it -- was it cut through or was it just
 23 scored?
 24 A. I believe it was cut through.
 25 Q. And is that the same with the PACU blanket as

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1 well, as of 1989 the blanket that was being sold by
 2 Augustine?
 3 A. I believe so.
 4 Q. So when the consumer got the blanket there
 5 would be a hose card with a circular opening with an X cut
 6 through the plastic, is that your understanding?
 7 A. As I recall.
 8 Q. With respect to -- that's with respect to the
 9 PACU that was sold in 1989?
 10 A. Yes.
 11 Q. And that's with respect to the lower body
 12 blanket that was -- that was shown at the 1989 trade show?
 13 A. I believe so.
 14 Q. When you -- you said you -- part of what you
 15 did during the show was to walk around the other exhibits.
 16 Do you recall seeing a Vital Signs exhibit at the show?
 17 A. I don't recall specifically.
 18 Q. Do you recall seeing a Gaymar exhibit?
 19 A. Not specifically, no.
 20 Q. How about a Cincinnati Subzero exhibit?
 21 A. Not specifically.
 22 Q. Do you recall seeing a Mallinckrodt exhibit?
 23 A. Not specifically, no.
 24 Q. Did you collect literature from the booths
 25 that you visited?

1 A. I don't recall.
 2 Q. Do you recall actually visiting any booths or
 3 do you recall just walking around the show?
 4 A. I think I visited with some booths.
 5 Q. Do you recall which ones you visited?
 6 A. I do not.
 7 Q. Do you recall seeing anyone from Mallinckrodt
 8 at the show?
 9 A. I do not.
 10 Q. Do you recall seeing any other products other
 11 than Augustine at the show? Can you recall any other product
 12 that you saw at the show aside from Augustine's?
 13 A. Not specifically, no.
 14 Q. Take a moment and look through the brochure
 15 marked as Exhibit 4 and then tell me whether you see any
 16 reference to any model numbers in there?
 17 A. I don't no.
 18 Q. Do you recall when Augustine decided upon a
 19 model number for its lower body O.R. blanket?
 20 A. I do not.
 21 Q. Do you know whether the lower body O.R.
 22 blanket had a model number at the time of the show, the '89
 23 show?
 24 A. Not for certain I don't.
 25 Q. How about the upper body blanket, do you know

1 whether the upper body blanket shown at the 1989 trade show
 2 was referred to by a model number?
 3 A. I don't recall.
 4 Q. Do you recall what the model number was of the
 5 first upper body blanket that was sold to customers was?
 6 A. I don't recall.
 7 Q. Do you know what the model number was of the
 8 upper body blanket that had a single hose connection opening
 9 was?
 10 A. I don't recall.
 11 Q. The photograph in the -- in the middle of the
 12 brochure of Exhibit 4, the -- the hose card that does not
 13 have a hose in it, does that picture show any means to
 14 facilitate the customer inserting the hose in to the plastic?
 15 A. It's not obvious from looking at the picture
 16 here, no.
 17 Q. Do you see anything in the picture that
 18 would -- would show that?
 19 A. No, I don't.
 20 Q. Do you see anything in any of these three
 21 photographs of Exhibit 1, 2, 3 that would show that?
 22 A. I do not.
 23 Q. Do you know if someone at Augustine was in
 24 charge of taking orders from customers at the show, the '89
 25 trade show?

1 A. I do not.
 2 Q. Who would it have been if there was someone
 3 that would have been taking orders do you know?
 4 MS. SORANNO: Objection, calls for
 5 speculation.
 6 A. I couldn't say for certain.
 7 BY MR. KURZ:
 8 Q. Does Augustine usually take orders for
 9 products at its trade shows?
 10 MS. SORANNO: Objection, lack of
 11 foundation.
 12 A. I couldn't say for certain.
 13 BY MR. KURZ:
 14 Q. Do you ever recall Augustine taking any orders
 15 for products at its trade shows?
 16 A. I think we generate lead cards for -- for
 17 hospitals.
 18 Q. Do you ever recall anyone at Augustine ever
 19 taking any orders for products at trade shows?
 20 A. Not that I recall, no.
 21 Q. Do you recall distributing any lead cards at
 22 the 1989 trade show?
 23 A. Not specifically, no.
 24 Q. Do you know if any lead cards were distributed
 25 at the 1989 trade show?

1 A. I couldn't say for certain.
 2 Q. Do you know how many people visited the
 3 Augustine booth at the 1989 trade show?
 4 A. I do not.
 5 Q. You don't have any recollection at all?
 6 A. I remember we were busy.
 7 Q. Do you remember whether it was more than
 8 50 people?
 9 A. I'm certain.
 10 Q. You're certain it was more than 50?
 11 A. Yea.
 12 Q. Are you certain it was more than a hundred?
 13 A. Yea.
 14 Q. Are you certain it was more than 200?
 15 A. Yea, I'm pretty sure.
 16 Q. Over the course of how many days did you come
 17 to an understanding that there were over 200 people who
 18 visited the Augustine booth at the '89 trade show?
 19 A. Over the couple, two or three days, I think,
 20 that I was at the booth.
 21 Q. And you personally saw over 200 people come
 22 through the Augustine booth?
 23 A. I couldn't say for certain, no.
 24 Q. How do you know that there were over 200
 25 people that visited the Augustine booth?

1 A. I guess I would just estimate that from the
2 number of -- of people that I recall talking with and
3 visiting with.
4 Q. How many demonstrations did you give of the
5 product do you remember?
6 A. I don't know that we gave demonstrations
7 per se. I mean, the product was there to look at and anytime
8 customers came in to the booth we explained what it was that
9 we had.
10 Q. How many explanations would you say you gave
11 of the upper body blanket?
12 A. I just don't recall.
13 Q. Would it have been more than 20?
14 A. Probably.
15 Q. Would it have been more than 50?
16 A. I don't know.
17 Q. Who would have been responsible for the --
18 strike that. You say you recall that there were over
19 200 people who visited the Augustine booth, is that right?
20 A. I'm guessing that there probably were that
21 many, yes.
22 Q. You say you're guessing?
23 A. Yes.
24 Q. So you're not sure that there were more than
25 200?

1 A. Well, I wasn't counting them.
2 Q. Do you know who else gave -- gave explanations
3 of the products that were shown at the Augustine booth aside
4 from yourself?
5 A. Everyone that was working the -- the trade
6 show booth.
7 Q. And that would be Sue Dykins, Doug Augustine,
8 Scott Augustine?
9 A. That's the ones that I remember. There could
10 have been others.
11 Q. Do you remember Sue Augustine being at the
12 show?
13 A. That's Sue Dykins.
14 Q. That was before she became Sue Augustine, is
15 that right? You're referring to the same person?
16 A. Yes, that's the same person, yes.
17 Q. Did there come a time that Augustine decided
18 to change the design of the upper body blanket that's shown
19 in Exhibit 1 and Exhibit 4 to provide only a single entry
20 port?
21 A. Yes.
22 Q. Do you recall approximately when that was?
23 A. I don't recall.
24 Q. Were you involved in the design of the upper
25 body blanket that incorporated that change?

1 A. I believe so.
2 Q. Who else was involved?
3 A. Dr. Augustine perhaps.
4 Q. Anyone else that you recall?
5 A. I don't recall.
6 Q. What -- what did you do designwise to change
7 the upper body blanket to go from a design that showed two
8 nozzle entrances to one that had only one?
9 A. I don't recall specifically.
10 Q. You don't recall anything about the design
11 changes that you made?
12 A. I don't know.
13 Q. Do you know whether it was anything more than
14 just not applying the hose card to one portion of the
15 blanket?
16 A. I don't recall.
17 Q. Do you recall whether the intention was --
18 with respect to the upper body blanket shown in Exhibit 1 do
19 you recall whether the intention was to -- to actually sell
20 products, upper body products to customers that had two hose
21 cards on them or whether it was to sell a product that had
22 either a hose card on one side or the other?
23 A. I believe the intent was to sell upper body
24 covers with two hose cards.
25 Q. Are you certain of that?

1 A. To the best of my recollection.
2 Q. Do you know why it was decided that Augustine
3 would offer a upper body blanket that had only one hose card
4 on it?
5 A. As I recall, we were getting feedback from
6 clinicians that a majority of them were only using the one
7 port.
8 Q. Do you have an understanding that clinicians
9 actually used Augustine upper body blankets with two hose
10 cards on it?
11 A. I don't recall.
12 Q. But you said that it was your understanding
13 that you had feedback from clinicians that they were only
14 using one port. Is that not with respect to Augustine
15 blankets?
16 A. Yes.
17 Q. So you understand that there was feedback from
18 clinicians that they were only using one port?
19 A. Yes.
20 Q. Is that one port of the two ports that were
21 available on upper body blankets?
22 A. I believe so.
23 Q. But you don't have an understanding as to
24 whether clinicians ever used Augustine's upper body blanket
25 that had two ports, is that right?

1 A. I believe they did.
 2 Q. You believe they did?
 3 A. Yes.
 4 Q. And you believe that they did prior to 1991?
 5 A. I don't recall.
 6 Q. So you don't know whether clinicians used an
 7 Augustine upper body blanket with two hose cards prior to
 8 1991, is that correct?
 9 A. I just - I'm not for certain.
 10 Q. Do you know for certain that there was
 11 feedback from clinicians that they only used one port prior
 12 to 1991?
 13 A. I believe so.
 14 Q. Have you seen - how did you obtain that
 15 feedback?
 16 A. I would assume from Dr. Augustine.
 17 Q. Did he tell you this or show you something in
 18 writing?
 19 A. I don't recall.
 20 Q. Do you know which clinicians he might have
 21 been referring to?
 22 A. I do not.
 23 Q. Okay. With respect to the - the single port
 24 upper body blankets that Augustine sold do you recall whether
 25 the hose card on that blanket was essentially the same as the

1 blanket?
 2 A. I don't recall.
 3 Q. Do you recall any discussions regarding cost
 4 as being a factor?
 5 A. I don't recall.
 6 Q. Do you recall that there came a point in time
 7 when - when Augustine began selling a dual port upper body
 8 blanket after this 1989 time frame?
 9 A. Yes.
 10 Q. Do you recall approximately when that was?
 11 A. I do not.
 12 Q. Let me hand you a document that was marked as
 13 Exhibit 1 to the Anderson deposition yesterday and have you
 14 take a look at that, particularly on Page 2 under the heading
 15 "When Our Customers Talk We Listen". Does that refresh your
 16 recollection as to when Augustine started selling dual port
 17 upper body blankets subsequent to the 1989 time frame?
 18 A. I don't recall, but this could be the time
 19 that it happened.
 20 Q. When you say "this" you're saying the
 21 reference to 1990 - early 1993?
 22 A. Yes.
 23 Q. Were you involved in the redesign of the upper
 24 body blankets to change them from being single port blankets
 25 to being dual port blankets?

1 hose card used in connection with the blankets that are
 2 depicted in Exhibits 1 and 4?
 3 A. I believe so.
 4 Q. Now, the single hose card models that were
 5 sold by Augustine was the plastic within the open circle of
 6 the hose card cut prior to the customer receiving it like was
 7 done with the PACU and the lower body blankets?
 8 A. I believe so.
 9 Q. Do you know how this cutting was made? Was it
 10 done with a machine or was it done by a person?
 11 A. I believe it was just done by a person with a
 12 razor knife.
 13 Q. And this was done by a person at Augustine?
 14 A. I believe so.
 15 Q. In manufacturing?
 16 A. I believe so.
 17 Q. Do you know whether this cut was made after
 18 the hose card was applied or before the hose card was
 19 applied?
 20 MS. SORANNO: Objection, lack of
 21 foundation.
 22 A. I believe it was done afterwards.
 23 BY MR. KURZ:
 24 Q. Any other reasons that you were aware of why
 25 Augustine decided to go with a single opening upper body

1 A. I believe so.
 2 Q. Do you recall how long that redesign work
 3 took?
 4 A. I don't recall.
 5 Q. Was it closer to a month or closer to a year?
 6 A. I don't recall.
 7 Q. It could have been as long as a year you
 8 worked on that change?
 9 A. I don't think so.
 10 Q. Could it have been as little as a month?
 11 A. It could have been, but I just don't recall.
 12 Q. And do you recall what design changes were
 13 made to the upper body blanket to change it from a single
 14 port model to a dual port model?
 15 A. I believe we designed a new flag or hose card.
 16 Q. Who was involved in the design of the new hose
 17 card?
 18 A. I was for one, I don't recall others.
 19 Q. Was Tom Anderson?
 20 A. Could have been.
 21 Q. Who was primarily responsible for that?
 22 A. I don't recall.
 23 Q. Could it have been you?
 24 A. Could have been.
 25 Q. Any other changes you recall, aside from

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1 designing a new hose card, that were made from -- going from
 2 a upper body single port blanket to an upper body dual port
 3 blanket?
 4 A. You mean to facilitate that change?
 5 Q. Yes.
 6 A. No.
 7 Q. This is a drawing that was made by
 8 Mr. Anderson yesterday, I'll show you it's Anderson
 9 Exhibit 3.
 10 A. Okay.
 11 Q. Does this comport with your understanding of
 12 how the hose card was -- the finalized version of the hose
 13 card that was used in connection with the dual port upper
 14 body blanket?
 15 A. In the second release, yes.
 16 Q. What was the first release?
 17 A. It was our traditional card here.
 18 Q. When you say the second release you mean the
 19 release in 1983, in 1993, approximately 1993?
 20 A. Yea.
 21 Q. And you're distinguishing that from the hose
 22 card that was used as shown in the photograph of Exhibit 1,
 23 for example?
 24 A. I believe so, yes.
 25 Q. Can you explain in your own words the

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1 construction of the hose card that's shown in Exhibit 3?
 2 A. Again, it was just a paper-like cardboard
 3 structure with a adhesive backer on two sides, I believe.
 4 Q. Which two sides?
 5 A. I believe both faces of the A, the front side
 6 and the back side had adhesive on them.
 7 VIDEO TECHNICIAN: Excuse me, I'm going to
 8 interrupt you here to change the video. Going off the video
 9 record.
 10 (Whereupon, a brief off the record
 11 discussion was held.)
 12 VIDEO TECHNICIAN: Continuing with video
 13 record, Tape Number 2.
 14 BY MR. KURZ:
 15 Q. Continuing with your explanation, was the --
 16 in looking at the A portion of Exhibit 3 was there a cut-out
 17 portion here where there was no cardboard in this circle of
 18 A?
 19 A. I believe so.
 20 Q. And continue with your explanation as to how
 21 the card was -- what the characteristics of the card were.
 22 A. I believe the -- you peeled the liner off the
 23 back side of the A portion and adhered it to the blanket, and
 24 I don't remember whether they pierced the plastic or not.
 25 And then removed the liner from the front of the A side and

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1 then folded along the score line and mated the B half with
 2 the A half. And the B half had a plug that was scored which
 3 was removable.
 4 Q. When you say "a plug that was scored" are you
 5 referring to this dotted line circle shown --
 6 A. The score line, yes.
 7 Q. -- in B? And you say you don't recall whether
 8 the -- the blanket within the hole of circle A was cut prior
 9 to it being sent to customers?
 10 A. I don't recall.
 11 Q. And do you recall -- rather strike that. Tom
 12 Anderson testified yesterday that once this was affixed to
 13 the blanket and sold to the customer the customer would
 14 either push the cardboard in to the blanket or tear the
 15 cardboard away from the blanket, is that --
 16 MS. SORANNO: Objection, mischaracterizes
 17 his testimony.
 18 BY MR. KURZ:
 19 Q. Is that your understanding as well?
 20 MS. SORANNO: Lack of foundation.
 21 A. I couldn't say for certain.
 22 BY MR. KURZ:
 23 Q. Do you disagree with his characterization as
 24 I've told you?
 25 A. I don't recall what the instructions on the

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1 card instructed the clinician to use. I think there was
 2 instructions for use printed on the card.
 3 Q. Do you have any knowledge of how -- how users
 4 actually used the entry nozzle way?
 5 A. I do not.
 6 Q. Do you know why Augustine decided to go from a
 7 single port upper body blanket to a dual port upper body
 8 blanket?
 9 A. I believe we were getting requests from our
 10 customers.
 11 Q. Did you ever see any of those requests?
 12 A. Not specifically, no.
 13 Q. Did you ever talk to any customers about those
 14 requests?
 15 A. I don't believe so.
 16 Q. Did you ever talk to anyone at Augustine
 17 regarding those customer requests?
 18 A. Not specifically that I recall, no.
 19 Q. At the time that you began this redesign to
 20 add a second port to the upper body blanket, you were aware
 21 that Mallinckrodt had a dual port upper body blanket weren't
 22 you?
 23 A. No, I'm not for certain.
 24 Q. You're not for certain?
 25 A. No.

1 Q. Do you think you were aware?
 2 A. Probably.
 3 Q. And what were -- you indicated that the reason
 4 for going to the dual port upper body blanket was feedback
 5 from clinicians, is that right?
 6 A. I was responding to what the marketing
 7 department was telling me.
 8 Q. And what -- who -- what did the marketing
 9 department tell you?
 10 A. We had a request to engineer an upper body two
 11 port blanket.
 12 Q. Did they mention to you that Mallinckrodt had
 13 a two port upper body blanket?
 14 A. I don't recall.
 15 Q. Do you recall who you spoke with at -- at
 16 marketing?
 17 A. I don't.
 18 Q. Who would be the person who would normally
 19 communicate marketing's design changes to you?
 20 A. It could be anybody from marketing. We've had
 21 a lot of turnover in marketing over the years.
 22 Q. Do you recall who would have been the person
 23 to indicate design changes in the early 1993 -- strike that,
 24 in the 1993 time frame?
 25 A. I do not.

1 Q. Do you recall having any discussions with
 2 Scott Augustine regarding changing from a single port upper
 3 body blanket to a dual port upper body blanket?
 4 A. Not specifically, no.
 5 Q. How about generally?
 6 A. It could have happened, I don't know.
 7 Q. Do you recall discussing those types of
 8 changes with anyone other than the marketing department?
 9 A. I probably discussed it with engineering or
 10 production to see what the ramifications would have been.
 11 Q. What did they indicate the ramifications would
 12 be?
 13 A. I don't recall.
 14 Q. Do you recall whether there was a change in
 15 the way the surgeons -- strike that. Do you recall whether
 16 there was a change in the way operating rooms were set up
 17 that facilitated the need for a hose opening on either side
 18 of the upper body blanket?
 19 MS. SORANNO: objection, lack of
 20 foundation.
 21 A. No, not that I recall.
 22 BY MR. KURZ:
 23 Q. When you started the redesign of the upper
 24 body blanket to go from a single port to two ports did you --
 25 did you consider using the design that was used back in 1989?

1 A. I don't recall.
 2 Q. Do you recall preparing any prototypes with
 3 the design of two ports that were akin to the design of the
 4 blanket shown in Exhibit 1?
 5 A. I don't recall.
 6 Q. Do you recall any discussions regarding the
 7 possibility of using a dual port design that was the same as
 8 the 1989 design?
 9 A. I don't recall.
 10 Q. Do you recall why it was that you just didn't
 11 use the same design that you used in 1989?
 12 A. I just don't recall.
 13 Q. Do you recall whether you -- strike that.
 14 Were there any drawings that you're aware of of the 1989 dual
 15 port design, design drawings?
 16 A. I couldn't be for certain.
 17 Q. Did you look at any when you were attempting
 18 to redesign the product in 1993 -- strike that. Did you look
 19 at any such drawings when you were attempting to redesign the
 20 upper body blanket to go from a single port design to a dual
 21 port design?
 22 A. I don't recall.
 23 Q. Why was there a need to redesign the hose card
 24 to use in connection with a dual port upper body design?
 25 A. I think at the same time we were incorporating

1 that change we were lowering the -- the loft on the blankets
 2 and there was less plastic in the upper layer. And the --
 3 the vertical dimension on these hose cards was kind of
 4 extreme, so we went to a design that had a lower profile to
 5 it.
 6 Q. Was the -- any other reasons?
 7 A. It could have been that we were looking to
 8 gain some more surface area, too, for -- for labeling, but I
 9 couldn't say for sure.
 10 Q. Were you also looking to make a design that
 11 would facilitate the user's choice of opening one opening or
 12 the other?
 13 A. I believe so, yes.
 14 Q. Isn't that one of the reasons why you wanted
 15 to redesign the hose card?
 16 A. That was one thing we were looking for when we
 17 were redesigning, yes.
 18 Q. When you were redesigning the hose card did
 19 you consider having a card that did not have a cardboard
 20 perforated circular center in favor of having a circular
 21 opening where a hose could be inserted directly through
 22 sealed plastic?
 23 A. I don't recall.
 24 Q. You don't recall whether you considered that
 25 when you were redesigning the single port to the dual port?

1 A. I just recall we looked at a number of
2 different possibilities or prototypes.
3 Q. What possibilities and prototypes do you
4 recall?
5 A. I have no recollection hardly at all.
6 Q. Did you make drawings of the various
7 prototypes that you were working on in 1993 - strike that.
8 Did you have drawings or make drawings of the prototypes that
9 you were making in connection with the redesign of the
10 blanket to go from one port to two ports?
11 A. I don't believe so.
12 Q. Did you keep a notebook at that time?
13 A. I did not.
14 Q. When did you start keeping a notebook?
15 A. About a year and a half ago.
16 Q. Did you make notes regarding the various
17 designs that you tried with respect to designing a dual port
18 as opposed to a single port upper body blanket?
19 A. I did not keep notes, no.
20 Q. Did you take photographs of prototypes that
21 you were designing at that time?
22 A. I did not.
23 Q. Did you save the prototypes?
24 A. I don't believe so.
25 Q. You drew them out?

1 A. Probably.
2 Q. Do you recall having any - strike that. Are
3 you - is Augustine currently using the hose card that -- of
4 the design that you -- strike that. Did there come a time
5 that Augustine incorporated the hose card that you described
6 and is described in or shown in Anderson Exhibit 3?
7 A. What was that question again?
8 Q. Did there come a time - this hose card that's
9 shown in Exhibit 3 and that you described, that's the hose
10 card that was eventually used in the upper body dual port
11 blanket, right?
12 A. Yes, yes.
13 Q. Is that the same design that's still used
14 today?
15 A. I don't believe so.
16 Q. What changes have been made?
17 A. I believe it's now rather than a double card
18 that's folded over I think it's a single one of a smaller
19 size and then there's a little plastic plug that fits in the
20 hole.
21 Q. What type of a plastic plug?
22 A. It looks like a little cloverleaf. It flexes
23 and fits in the hole.
24 Q. Could you draw it for me?
25 A. Sure.

1 Q. Why don't we get you a pen. Here you go. Why
2 don't you go ahead and just show me the card with the opening
3 and how the opening is sealed.
4 A. I think the card is basically square. I could
5 be mistaken, but rounded corners and an opening. And then
6 the plug is a - when you flex the plug from two sides it
7 flexes under, two sides would lay on top here and two would
8 be on the inside of the blanket.
9 Q. And then is that - is that intended to be
10 replaceable by the user or once it's removed it can't be
11 replaced?
12 A. No, the user could place that in either side
13 of the blanket they wished to.
14 Q. Is it sold - is the plug sold detached from
15 the blanket, I mean, detached from the card?
16 MS. SORANNO: objection, lack of
17 foundation.
18 A. I couldn't say for certain.
19 BY MR. KURZ:
20 Q. When was this design - when was the change
21 made from the hose card shown in Exhibit 3 - why don't we go
22 ahead and label this, to facilitate discussion, as the next
23 - next exhibit.
24 (Whereupon, ARNOLD Deposition Exhibit
25 Number 5 was marked for identification)

1 by the court reporter.)
2 BY MR. KURZ:
3 Q. Okay. Is the -- are products -- upper body --
4 is this design that you've shown in Arnold Exhibit 5
5 incorporated in all of Augustine's blankets?
6 A. I don't believe so.
7 Q. Is it incorporated in to any of them that are
8 being sold now?
9 A. The upper body, I believe.
10 Q. Any others?
11 A. Not that I'm aware of.
12 Q. When you say "upper body" you mean arms out
13 upper body?
14 A. Yes.
15 Q. Are the other models using the design that's
16 shown in Anderson Exhibit 3 which you described?
17 A. I believe they're a design similar to this.
18 Q. Which is Anderson 5?
19 A. I believe so.
20 Q. Was the design of Anderson 3 ever used in
21 any - any Augustine blanket other than the upper body arms
22 out blanket?
23 A. Not that I recall.
24 Q. Were the hose widths decreased to lower the
25 loft in connection with blankets other than the upper body

1 arms out blankets?
 2 A. I believe so.
 3 Q. Was the hose card ever redesigned -- strike
 4 that. You mentioned that one of the considerations in
 5 redesigning the hose card in the upper body blanket to that
 6 as shown in Exhibit 3 was to accommodate the smaller diameter
 7 tubes?
 8 A. Yes.
 9 Q. Was any such change made in the hose cards for
 10 the other blankets to accommodate smaller diameter tubes?
 11 A. It wasn't necessary by virtue of the fact that
 12 the hose was addressing the -- the tube at a different angle
 13 on -- on other products.
 14 Q. Could you go in to some detail about what that
 15 difference was with the hose angle and why it wasn't
 16 necessary?
 17 A. Well, on our other blankets this card is -- is
 18 mounted in line with the length of the tube, and how long it
 19 is is really irrelevant. On the upper body blanket this was
 20 mounted transverse to the tube, and the longer it was the
 21 more it wanted to go up and around the curvature, and less
 22 was better.
 23 Q. When did Augustine begin selling blankets that
 24 incorporated the hose card design that you've depicted in
 25 Arnold Exhibit 5?

1 Q. Do you have notes and drawings of your design
 2 of the hose card in Exhibit 5?
 3 A. I do not.
 4 Q. Did anyone -- is it your normal practice in
 5 the last year and a half to make notes and drawings of design
 6 changes that you make?
 7 A. When it's a product that I'm a primary
 8 engineer on, yes.
 9 Q. Who's the primary engineer of the hose card of
 10 Arnold Exhibit 5?
 11 A. Tom Anderson.
 12 Q. When you're not the primary engineer of a
 13 product you don't take any notes at all?
 14 A. Generally not.
 15 Q. Or make any drawings?
 16 A. Generally not.
 17 Q. Do you know whether Mr. Anderson made any
 18 notes or drawings of the design of the hose card of
 19 Exhibit 5?
 20 A. I couldn't say for certain.
 21 Q. Have you ever seen any?
 22 A. I don't recall.
 23 Q. Have there been any other nozzle entry designs
 24 that Augustine ever incorporated in to a blanket which it
 25 sold other than the designs of Anderson Exhibit 5 and 3 and

1 MS. SORANNO: Objection, lack of
 2 foundation.
 3 A. I don't know.
 4 BY MR. KURZ:
 5 Q. Do you know if blankets are currently being
 6 sold that have the hose card design in Exhibit 5?
 7 A. I believe so.
 8 Q. Do you know approximately when that was begun?
 9 A. I couldn't say for certain.
 10 Q. Was it within the past year?
 11 MS. SORANNO: Objection, lack of
 12 foundation.
 13 A. I believe so, but I couldn't say for certain.
 14 BY MR. KURZ:
 15 Q. Did you work on the redesign of the hose card
 16 -- strike that. Did you work on the design of the hose card
 17 that's depicted in Exhibit 5?
 18 A. I did.
 19 Q. Who else worked on that?
 20 A. Tom Anderson.
 21 Q. Anyone else?
 22 A. Not that I can say for certain, no.
 23 Q. And you say that for the last year and a half
 24 you've kept a notebook, right?
 25 A. Yes.

1 Arnold Exhibit 5?
 2 A. I believe so, but I couldn't say for certain.
 3 Q. Do you recall any changes of any other nozzle
 4 --
 5 A. I think we have a --
 6 Q. Strike that, I did not complete the question.
 7 Can you describe any characteristics of any other hose card
 8 A. I think we have a small rectangular hose card
 9 that's used with our -- our pediatric line of blankets.
 10 Q. Who designed that hose card?
 11 A. I couldn't say for certain.
 12 Q. Were you involved in its design?
 13 A. Possibly.
 14 Q. Do you know approximately when it was
 15 designed?
 16 A. When we introduced the pediatric line of
 17 blankets.
 18 Q. Who else besides yourself would have been
 19 involved in the design of that card?
 20 A. I couldn't say for certain.
 21 Q. Does that card have a -- a open hole in the
 22 cardboard or a -- or is it closed with cardboard or anything
 23 else?
 24 MS. SORANNO: Objection, lack of
 25 foundation.

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1 A. I believe it's open.
2 BY MR. KURTZ:
3 Q. Is the blanket within the open circle of the
4 base card cut prior to the customer receiving the blanket?
5 MS. SORANNO: objection, lack of
6 foundation.
7 A. I believe so, but I couldn't say for certain.
8 MS. SORANNO: Counsel, let's go off the
9 record and talk about timing here.
10 VIDEO TECHNICIAN: Going off video record.
11 (Whereupon, a brief off the record
12 discussion was held.)
13 (Whereupon, a lunch recess was taken
14 from 12:10 to 1:30.)
15 VIDEO TECHNICIAN: Continuing with video
16 record.
17 MR. KURTZ: During the break we had a
18 discussion about what to do about the exhibits that have been
19 marked in connection with this deposition, which exhibits
20 constitute the three original photographs of the - of what
21 purport to be the 1989 trade show, A.S.A. show in New Orleans
22 and the original of the "Normothermia In The O.R." brochure.
23 And Augustine counsel has indicated that she will not
24 relinquish those originals to become to our possession or to
25 the possession of the court reporter to - to go along with

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1 the original deposition. So what we have done is we have
2 color photocopies of those exhibits, which we will mark with
3 numbers that correspond to the originals but maybe we'll put
4 an A next to each one so we'll know that they -
5 MS. SORANNO: That's fine.
6 MR. KURTZ: - correspond to them, with the
7 understanding that we can have reasonable access to the
8 originals as reasonably requested.
9 MS. SORANNO: Yep, that's fine.
10 MR. KURTZ: Okay.
11 (Whereupon, ARNOLD deposition Exhibit
12 Numbers 1A - 4A were marked for identification
13 by the Court Reporter.)
14 BY MR. KURTZ:
15 Q. Let me hand you a document that's entitled
16 "Memorandum In Support of Defendant Augustine Medical, Inc.'s
17 Motion For Summary Judgment". Have you seen that before?
18 A. I don't recall.
19 Q. Okay, I'd like to direct your attention to
20 some statements that were made in the - in the memorandum.
21 If you could turn to Page 4, please? In the first paragraph
22 there's a statement there that says, "The 1989 annual meeting
23 of the American Society of Anesthesiologists, 1989 A.S.A.
24 meeting, was held in New Orleans from October 14 to
25 October 18".

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1 And then it says, "Exhibit I to the affidavit of
2 J. Randall Benham, Augustine Medical maintained a display
3 booth during the entire period". Then it says, "Affidavit of
4 Dr. Scott D. Augustine". Then it says, "On display at the
5 booth was the Bair Hugger dual port upper body blanket, a
6 product substantially identical to the blanket Mallinckrodt
7 has accused of patent infringement". Do you see that?
8 A. I see that.
9 Q. Do you agree that the product on display at
10 the booth was substantially identical to the blanket that
11 Mallinckrodt has accused of patent infringement?
12 MS. SORANNO: objection, lack of
13 foundation.
14 A. I'm not sure.
15 BY MR. KURTZ:
16 Q. You're not sure. Looking at Page 14 it says
17 - right before the conclusion there's a paragraph that says,
18 "Mallinckrodt claims that Augustine Medical's dual port upper
19 body blanket infringes the 924 and 439 patents". Then it
20 says, "The same blanket, however, was invented, known by
21 others or on sale more than one year prior to Mallinckrodt's
22 alleged date of infringement". Do you consider - I'm sorry,
23 I read that wrong, "and on sale more than one year prior to
24 Mallinckrodt's alleged date of invention", I think I said
25 "infringement", sorry. Do you have an opinion as to whether

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1 the - the blanket that was on sale - strike that, the
2 blanket that was shown at the 1989 trade show is the same
3 blanket as, for example, the Augustine 522 blanket? Do you
4 consider them to be the same?
5 A. I do, yes.
6 Q. You do?
7 A. Yes.
8 Q. Can you tell me if - are there any
9 differences between the two blankets?
10 A. Manufacturing techniques have changed a lot,
11 but.
12 Q. Your opinion is the blankets themselves are
13 substantially identical?
14 A. Substantially the same, serve the same
15 function.
16 Q. Well, serving the same function doesn't mean
17 they're the same does it? Or does it to you?
18 A. Well, specifically what are you asking?
19 Q. I'm asking you whether the construction of the
20 blanket was the same, is that a fair characterization that
21 the blanket shown at the 1989 trade show is the same as the
22 Augustine 522 blanket?
23 A. No, there's differences.
24 Q. So you disagree with the statement in the
25 brief then, right? I'll tell you what, why don't we look at

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1 the -- why don't we look at this blanket, you can tell me
2 what's the same and what's different, okay? Do you recognize
3 this blanket that's on the table here as the Augustine 522
4 model blanket?
5 A. I recognize it as being an upper body blanket.
6 I'm not sure of the model number.
7 Q. Okay, for the record -- I'm going to need to
8 move around here a little bit, I think.
9 MR. KURZ: Let me go off the record for
10 one second.
11 VIDEO TECHNICIAN: Going off video record.
12 (Whereupon, a brief off the record
13 discussion was held.)
14 VIDEO TECHNICIAN: Continuing with video
15 record.
16 BY MR. KURZ:
17 Q. For the record, this blanket came out of a
18 package that had this card in it. Do you have any reason to
19 believe that the blanket in front of you is not the dual port
20 upper body model 522 Augustine blanket?
21 A. Of the current design or of a design?
22 Q. A design of a model 522?
23 A. I believe so.
24 Q. You believe that it is?
25 A. Yes.

1 Q. Okay. What I'd like to do is inflate the
2 blanket and then I would like to go feature by feature or
3 characteristic by characteristic and have you tell me what's
4 the same or different as between this blanket and the blanket
5 that was shown at the 1989 trade show, okay?
6 A. Okay.
7 MS. SORANNO: Do you want it on?
8 MR. KURZ: Sure. Thank you.
9 MS. SORANNO: Is it plugged in?
10 MR. KURZ: Yes.
11 MS. SORANNO: There we go.
12 BY MR. KURZ:
13 Q. Starting with the -- this plastic cover that
14 is in my hand here did the blanket that was shown at the 1989
15 trade show have a plastic cover like this?
16 A. I believe it did.
17 Q. Was it a cover that was substantially
18 identical to this one in appearance?
19 A. Pretty similar.
20 Q. What were the differences?
21 A. It might have been larger or smaller in size,
22 I don't recall. I don't believe that we attached them to the
23 blanket at that time.
24 Q. It wouldn't have been glued to the blanket
25 like this one, is that --

1 A. Right.
2 Q. Is that what you're saying?
3 A. That's what I'm saying.
4 Q. Was the blanket -- can you tell me just
5 looking at this what -- whether the blanket that was shown at
6 the trade show was constructed of parallel tubes like this
7 one is?
8 A. It was.
9 Q. And do you know if it had the same number of
10 tubes?
11 A. I believe it had more tubes.
12 Q. Do you know how many more?
13 A. Two or three more, I believe.
14 Q. Two or three more?
15 A. Yes.
16 Q. Did it have a border around it such as I'm
17 holding -- can you get this all on video when I'm touching it
18 all? For example, at this side we see extra material over
19 here. Did the blanket at the 1989 trade show have extra
20 material off the side like that?
21 A. I believe it did.
22 Q. And off of this other side as well?
23 A. Yes.
24 Q. And did it have a cut-out portion -- this is
25 the head end, is that correct?

1 A. Yes.
2 Q. Did it have a cut-out portion at the head end
3 like this?
4 A. Yes.
5 Q. And did it have -- see this little bit of
6 extra material here coming out of the head portion?
7 A. Yes.
8 Q. Did it have a border of extra material like
9 this is on this blanket?
10 A. Yes.
11 Q. And did it have excess material closing off at
12 the ends of the tubes over here? And I'm pointing to the
13 side of the head cut-out portion.
14 A. Yes.
15 Q. Did it have approximately the same amount of
16 material as is shown here?
17 A. I don't recall.
18 Q. But it had excess material like this?
19 A. Yes.
20 Q. Approximately the same?
21 A. I don't recall.
22 Q. And did it have -- and this is uninflated
23 material, is that right?
24 A. Yes.
25 Q. And that uninflated material on the sides of

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1 the head cut-out portion you say were present in the -- in
2 the blanket at the '89 trade show?
3 A. I believe so.
4 Q. And did it have an uninflated section of
5 material extending from the head end as I'm pointing to now
6 to the right and left sides of the cut-out?
7 A. I believe so.
8 Q. And going towards the -- what would you refer
9 to the opposite of the head end, would you call it the body
10 end or the foot end? What do you refer to that as?
11 A. Foot end.
12 Q. Foot end. On the foot end of the blanket did
13 it have uninflated material as is shown on this blanket
14 that's before you right now?
15 A. Somewhat similar, I believe.
16 Q. Somewhat similar?
17 A. Yea.
18 Q. Do you recall any differences?
19 A. I don't know if it was this wide necessarily,
20 but it had material.
21 Q. It had material?
22 A. Yes.
23 Q. An uninflated section?
24 A. Yes.
25 Q. Did it have a -- a cut-out? Do you see this

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1 arc-shaped cut-out for the torso?
2 A. It had a cut-out. It wasn't an arc at that
3 time.
4 Q. There was a cut-out though for the torso?
5 A. Yes.
6 Q. And did it have any means for affixing the --
7 the blanket at the torso end to the patient?
8 A. There was tape.
9 Q. There was tape. Was the tape affixed to the
10 blanket as this is here and then peeled off?
11 A. Yes.
12 Q. Similar to this design right here? Again, it
13 was not -- you say it was not in an arc shape?
14 A. It was not in an arc shape, no.
15 Q. But it had tape that was affixed to the bottom
16 of the blanket that you would then peel off and affix to the
17 patient?
18 A. Yes.
19 Q. And did it have --
20 A. No sense warming up the room anymore.
21 MS. SORANNO: Okay.
22 BY MR. KURZ:
23 Q. Did it have an uninflated portion extending
24 towards the foot end from the lower most -- when I say lower
25 closer to the body most tube?

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1 A. Well, this would be the closest to the body
2 most tube. There was a --
3 Q. I'm sorry.
4 A. There was a portion.
5 Q. Let's -- let me rephrase the question then.
6 Was there an uninflated portion extending between the lower
7 most tubes?
8 A. Yes.
9 Q. And I'm pointing -- can you get what I'm
10 pointing to on here, over here? And did those -- did those
11 -- did that uninflated portion meet the ends of tubes like
12 this does right here? Did it close off ends of tubes like
13 this does?
14 A. Yes, it did, yes.
15 Q. And did the uninflated portion on the -- on
16 the head side also close off tubes?
17 A. Yes.
18 Q. Can you think of any differences between the
19 blanket that's in front of you now and the blanket that was
20 at the '89 show that you can describe for me right now?
21 A. The tubes were -- the upper layer the tubes
22 had much more fabric in them, they were larger tubes. The
23 lower material was a tissue paper and plastic laminate
24 instead of this non-woven. The upper --
25 Q. When you say the lowest layer was tissue paper

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1 and laminate and what is this?
2 A. This is a non-woven synthetic.
3 Q. Okay. Anything else?
4 A. The upper portion was formed with polyethylene
5 and I believe this is polypropylene on this particular cover,
6 it's got the -- kind of a cloudy, milky look to it as opposed
7 to the clear polyethylene sheet that we use for the head
8 drape. The hose cards are of our subsequent design.
9 Q. When you say the hose cards in this blanket
10 that you're looking at now were of a subsequent design?
11 A. Yes. And there might be less tubes than what
12 the initial design was, I believe.
13 Q. Anything else?
14 A. Well, the shape of the cut-out here originally
15 was, I think, more angular than a nice arc. I think the
16 space at the head might have been a little bit narrower, but
17 I couldn't be for certain.
18 Q. Anything else?
19 A. I think that's primarily it.
20 Q. Okay.
21 MR. KURZ: Why don't we go off the record
22 for a minute.
23 VIDEO TECHNICIAN: Going off video record.
24 (Whereupon, a brief off the record
25 discussion was held.)

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1 VIDEO TECHNICIAN: Continuing with video
 2 record.
 3 BY MR. KURZ:
 4 Q. Okay, just to make sure that we've got this
 5 all on video, I'm just going to repeat a few things and try
 6 to confirm the different parts of the blanket that we were
 7 talking about. Why don't we go ahead and blow it up. When
 8 we were talking about the uninflated material at the -- at
 9 the head end, let me just show to the camera the material
 10 that we were -- some of the material we were talking about
 11 was over here, can you see that? This is material that
 12 extends on the bottom edge of the head cut-out. And you say
 13 that this material was material -- uninflated material such
 14 as this was in the blanket at the '89 trade show?
 15 MS. SORANNO: Objection, asked and
 16 answered.
 17 BY MR. KURZ:
 18 Q. Correct?
 19 A. Yes.
 20 Q. And holding up again the additional uninflated
 21 material closing off the tubes at the head end that we
 22 discussed, this material over here, and you indicated that
 23 the blanket at the 1989 trade show had such material, is that
 24 correct?
 25 MS. SORANNO: Objection, asked and

1 BY MR. KURZ:
 2 Q. And you indicated that there was uninflated
 3 material, which I'm showing now on the camera, at the foot
 4 end before we reach the indentation for the body that was
 5 also present on the 19 -- the blanket shown at the 1989 trade
 6 show, is that correct?
 7 MS. SORANNO: Same objection.
 8 A. Yes.
 9 BY MR. KURZ:
 10 Q. And there's -- that's at both ends of the
 11 indented portion, is that correct?
 12 A. Yes.
 13 Q. And you indicated that the blanket at the 1989
 14 trade show had a cut-out for -- to accommodate the body, is
 15 that it wasn't curved like this, is that correct?
 16 A. Yes.
 17 Q. And you indicated that there was uninflated
 18 material closing off tubes on the foot end of the blanket,
 19 like this, in the blanket that was shown in the 1989 trade
 20 show, is that correct?
 21 MS. SORANNO: Same objection.
 22 A. Yes.
 23 BY MR. KURZ:
 24 Q. And that there was uninflated material
 25 extending across this space, is that correct, in the blanket

1 answered.
 2 A. Yes.
 3 BY MR. KURZ:
 4 Q. And the material, additional uninflated
 5 material at the head end, aside from the cut-out portion was
 6 this material both to the left and right of the cut-out --
 7 you indicated that the blanket at the 1989 trade show had
 8 uninflated material extending such as this, is that correct?
 9 MS. SORANNO: Objection, asked and
 10 answered.
 11 A. Yes.
 12 BY MR. KURZ:
 13 Q. And then material -- you indicated that there
 14 was material extending beyond the ends of the tubes on both
 15 the left and right sides of the blanket, this is one such
 16 side, here is the other, and you indicated that the blanket
 17 at the 1989 trade show had such material, is that correct?
 18 MS. SORANNO: Same objection.
 19 A. Yes.
 20 BY MR. KURZ:
 21 Q. And that the blanket at the '89 trade show had
 22 a clear plastic head cover, but it wasn't affixed to the
 23 blanket, is that correct?
 24 MS. SORANNO: Same objection.
 25 A. I believe so, yes.

1 at the 1989 trade show?
 2 MS. SORANNO: Same objection.
 3 A. Yes.
 4 BY MR. KURZ:
 5 Q. And you also indicated that there was tape
 6 affixed to the underside of the blanket at the 1989 trade
 7 show that had a peel-off portion which would then be affixed
 8 to the torso of the body, is that correct?
 9 MS. SORANNO: Same objection.
 10 A. Yes.
 11 MR. KURZ: Why don't we go off the record.
 12 VIDEO TECHNICIAN: Going off video record.
 13 (Whereupon, a brief off the record
 14 discussion was held.)
 15 VIDEO TECHNICIAN: Continuing with video
 16 record.
 17 MR. KURZ: Why don't we mark -- we'll mark
 18 this blanket that we just looked at as the next Arnold
 19 exhibit, which would be Exhibit 6. We can mark that in a
 20 moment.
 21 BY MR. KURZ:
 22 Q. Okay. Okay, do you recognize this blanket
 23 that I've just placed in front of you as a model -- Bair
 24 Hugger model 525 lower body blanket?
 25 A. I refer to it as a lower body cover.

1 Q. You're not familiar with the model number?
 2 A. I don't usually use model numbers when I refer
 3 to blankets.
 4 Q. For the record, this came out of a package
 5 with this insert that says model 525. You see these -- this
 6 hose opening over here on this blanket that's in front of
 7 you, it has a sliced X through it or a cross through it?
 8 A. Yes.
 9 Q. Is that what you referred to before when you
 10 were talking about an X sort of cut that was made with
 11 respect to certain plastic openings in -- in Augustine
 12 blankets?
 13 A. Something similar to that.
 14 Q. Have you ever seen anything different than
 15 this as far as the opening in the plastic?
 16 A. Not that I recall.
 17 Q. And this cutting of this plastic is done prior
 18 to the customer getting the blanket isn't it? It's done at
 19 Augustine, right?
 20 A. Yes.
 21 Q. And that would be -- I don't know if -- you
 22 probably can't get that X on there, but I'll try to point it
 23 out. Before we -- before we do that, why don't we just turn
 24 it off one more second. Do you see this hose card on this
 25 blanket in front of you, is this substantially identical to

1 the hose card that was used in connection with the lower body
 2 blanket that was shown at the 1989 trade show?
 3 A. I think so. I believe so.
 4 Q. And it would be the same hose card that would
 5 have been used in connection with the upper body blanket at
 6 the trade show wouldn't it?
 7 A. I believe so, but I couldn't say for sure.
 8 Q. Can you think of any differences that there
 9 were between those hose cards and this one?
 10 A. Not that I recall.
 11 Q. Okay. I would like you to go through again
 12 and explain the similarities and/or differences between the
 13 blanket that's in front of you and the lower body blanket
 14 that was shown at the 1989 trade show, okay?
 15 A. Okay.
 16 Q. Did the blanket at the 1989 trade show, the
 17 lower body blanket, see this material on the side here, I'm
 18 just pointing it to the camera for a second, there's some
 19 uninflated material along this edge. Did the lower body
 20 blanket shown at the 1989 trade show have uninflated material
 21 along the two edges as this one does?
 22 A. Yes.
 23 Q. I'll just hold up this edge for the camera.
 24 This is the uninflated material that you were just referring
 25 to, correct?

1 A. Yes.
 2 Q. And was there uninflated -- was there an
 3 uninflated section extending from the ends of the tubes
 4 towards the patient's head on the blanket shown at the 1989
 5 trade show?
 6 A. Yes.
 7 Q. Was there a -- do you consider this to be an
 8 uninflated viewing area?
 9 MS. SORANNO: Objection, lack of
 10 foundation.
 11 BY MR. KURZ:
 12 Q. What's the purpose of this material do you
 13 know?
 14 A. It's to facilitate patient viewing and -- and
 15 provide areas for placing surgical instruments.
 16 Q. Was that the purpose of the uninflated area on
 17 the blanket shown at the 1989 trade show?
 18 A. I believe so.
 19 Q. Was there an uninflated area with -- that
 20 extended inward from the head most end of the blanket, as
 21 that which I'm showing here with my hand and showing the
 22 camera, at the blanket -- on the blanket at the 1989 trade
 23 show?
 24 A. I couldn't be for certain on that.
 25 Q. You don't remember?

1 A. I don't recall.
 2 Q. Was there any means for -- this is the head
 3 end, right?
 4 A. Yes.
 5 Q. Was there any means for affixing the
 6 uninflated edge here to the patient on the blanket at the
 7 1989 trade show?
 8 A. Yes, it had tape on it.
 9 Q. Was the tape affixed to it such as this is and
 10 then it would be peeled off and adhered to the patient?
 11 A. Yes.
 12 Q. Just as this is here?
 13 A. Similar, I think, I couldn't be for certain.
 14 Q. But it did have tape where you would peel off
 15 the tape and then affix it -- the tape was it affixed to the
 16 head end of the blanket?
 17 A. Yes.
 18 Q. And then you would peel off the backing of the
 19 tape and then affix the tape to the patient, is that correct?
 20 A. Yes.
 21 Q. Did the blanket at the 1989 trade show have
 22 any uninflated portion extending towards the foot end of the
 23 blanket?
 24 A. Yes, but it was not as substantial as what
 25 this portion is here.

1 Q. It was a smaller portion?
 2 A. Yes.
 3 Q. And it extended all the way across the bottom
 4 of the blanket?
 5 A. Yes.
 6 Q. Would you consider that to have been a foot
 7 drape?
 8 A. No, it didn't have a foot drape on it at that
 9 time.
 10 Q. It did not have a foot drape on it. Did --
 11 just for the record, this blanket has a series of openings on
 12 the bottom from which the air exits. Did the blanket at the
 13 trade show have a series of openings on the bottom from which
 14 the air exited such as this here?
 15 A. Yes.
 16 Q. And I assume the same thing is true with
 17 Exhibit 6 as far as holes on the bottom from which air
 18 exited, is that correct?
 19 A. Yes.
 20 Q. Did the blankets at the '89 trade show
 21 self-erect when they were inflated?
 22 A. Define the term.
 23 Q. Well, what do you think it means?
 24 A. Well, they inflated for use.
 25 Q. They inflated for use?

1 A. Yes.
 2 Q. Is that your understanding of the term
 3 self-erect?
 4 A. Yes.
 5 Q. Did they have a tendency to form an arch when
 6 they were inflated?
 7 A. When they were placed over the dummies on the
 8 O.R. table.
 9 Q. But when they weren't placed on dummies on the
 10 O.R. table they did not have a -- a tendency to form an arch?
 11 A. I couldn't be for certain.
 12 Q. Does this blanket here have a tendency to form
 13 an arch?
 14 A. If you place a body underneath it.
 15 Q. So as far as you're concerned the
 16 self-erecting feature of the blanket, the two blankets that
 17 you looked at today, is the same as the self-erecting feature
 18 of the blankets that were shown at the 1989 trade show?
 19 A. Fairly similar.
 20 Q. What was the difference, if any?
 21 A. Basically the same. There was more material
 22 on the top of the blankets at the '89 show, but the same
 23 basically.
 24 Q. And was there any material at the foot end of
 25 the blanket at the 1989 trade show for covering the feet?

1 A. Just the -- the short margin of material that
 2 was similar to like the -- the head end, I believe.
 3 Q. Did that cover the feet?
 4 A. I don't believe so.
 5 Q. Okay, why don't we turn it off. Oh, I'm
 6 sorry, before we do that, why don't we plug it in again.
 7 Sorry, one more -- I want to ask you whether you -- go ahead
 8 and turn it on. I just want to ask you whether you can
 9 recite any other differences between the blanket that's in
 10 front of you now and the lower body blanket that was shown at
 11 the 1989 trade show?
 12 A. The materials have changed again. I believe
 13 that this is a non-woven and the one at the trade show was a
 14 paper with tissue -- or tissue paper with plastic laminate.
 15 Q. You're talking about the bottom layer, right?
 16 A. The bottom layer. And the upper layer was a
 17 polyethylene plastic as opposed to this polypropylene.
 18 Q. Anything else?
 19 A. The addition of the foot drape. And I
 20 couldn't be for certain, but I think there might have been an
 21 additional two tubes on the outside edges.
 22 Q. Anything else?
 23 A. I think those are the primary ones. And then
 24 the possibility of -- I'm not certain about the -- the
 25 extension of the -- the viewing area down into the blanket at

1 the top end.
 2 Q. That's this over here?
 3 A. Yes.
 4 Q. Anything else? Did the blanket at the 1989
 5 trade show have a continuous seam all across this end over
 6 here?
 7 A. I believe so.
 8 Q. Okay, why don't we go ahead and turn this off.
 9 MR. KURZ: Let's have this marked as
 10 Exhibit Number 7, please.
 11 (Whereupon, ARNOLD Deposition Exhibit
 12 Numbers 6 and 7 were marked for identification
 13 by the court reporter.)
 14 THE WITNESS: Could I quick get another
 15 drink of water?
 16 MR. KURZ: Sure, why don't we take a
 17 few-minute break.
 18 MS. SORANNO: I'll get it for you.
 19 VIDEO TECHNICIAN: Going off video record.
 20 (Whereupon, a brief off the record
 21 discussion was held.)
 22 VIDEO TECHNICIAN: Continuing with video
 23 record.
 24 BY MR. KURZ:
 25 Q. Were you one of the individuals who helped

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1 design the addition of the foot drape to the lower body
 2 blanket?
 3 A. Yes.
 4 Q. And why was the foot drape added to the
 5 blanket?
 6 A. To provide a means of -- of enclosing the
 7 patient's feet and maintaining the warm air that was being
 8 distributed by our blankets.
 9 Q. Was it in response to any feedback from
 10 clinicians?
 11 A. I couldn't say for sure.
 12 Q. Do you have an understanding as to whether it
 13 was?
 14 A. I couldn't say for certain.
 15 Q. Are you familiar with a Augustine product
 16 known as the Polar Bair?
 17 A. Yes.
 18 (Whereupon, the Court Reporter was instructed
 19 to bind the following portion of the
 20 deposition transcript separately as
 21 Confidential Attorneys' Eyes Only.)
 22
 23
 24
 25

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1 (Whereupon, the following portion of the
 2 deposition transcript is labeled as
 3 Confidential Attorneys' Eyes Only.)
 4 BY MR. KURZ:
 5 Q. Can you tell me what that product is?
 6 A. Its --
 7 MS. SORANNO: Let's put this on the
 8 attorney/client -- or I'm sorry, the confidential attorneys'
 9 eyes only record. Go ahead.
 10 A. Its -- its current name is -- is the Polar
 11 Air. It was referred to as the Polar Air at one time.
 12 BY MR. KURZ:
 13 Q. The Polar Bair?
 14 A. Yes. It is now officially called the Polar
 15 Air.
 16 Q. Do you know why the name was changed?
 17 A. I believe it was a -- some trademark
 18 negotiations with another company.
 19 Q. And can you tell me what the product -- is the
 20 product currently being sold?
 21 A. Yes.
 22 Q. Do you know when the first sale of the product
 23 was?
 24 A. I do not.
 25 Q. Approximately how long ago did Augustine start

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1 selling the Polar Bair?
 2 MS. SORANNO: Objection, calls for
 3 speculation.
 4 A. I don't know.
 5 BY MR. KURZ:
 6 Q. Did you work on the Polar Bair project at all?
 7 A. Yes, I did.
 8 Q. What did you do in connection with the
 9 product?
 10 A. Early on in the product's development I was
 11 part of the team that was working on the project.
 12 Q. Did you continue to work on the project
 13 through its development?
 14 A. I continued to watch the progress of the
 15 development and offer advice from time to time when I had a
 16 particular idea about a way to solve a problem or something
 17 that they were running in to.
 18 Q. Did you -- do you recall what any of your
 19 contributions were to the project?
 20 A. Not specifically, no.
 21 Q. Do you know when work on the Polar Bair
 22 product began?
 23 A. Oh, I believe probably four to five years ago.
 24 Q. Do you know if the product's been on sale for
 25 more than a year now?

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1 MS. SORANNO: Objection, calls for
 2 speculation.
 3 A. I do not.
 4 BY MR. KURZ:
 5 Q. Do you know whether the -- do you know where
 6 the product was first sold?
 7 A. I do not.
 8 Q. Do you know whether it was sold outside of the
 9 United States before it was sold inside the United States?
 10 A. I don't know that.
 11 Q. Are you familiar with any clinical trials that
 12 occurred in connection with the Polar Bair product?
 13 A. I knew that we had some going, ongoing
 14 studies, but.
 15 Q. Do you know where they were occurring?
 16 A. I do not.
 17 Q. You can't think of one place that involved a
 18 clinical study of the Polar Bair?
 19 A. I believe we had one study going in Austria or
 20 Switzerland.
 21 Q. Do you know what institution in Austria or
 22 Switzerland was studying the product?
 23 A. I do not.
 24 Q. Can you think of any others?
 25 A. No, I can't.

1 Q. Have you ever heard any allegations that
2 Mallinckrodt employees improperly gained access to a Polar
3 Bair product?
4 A. Yes, I did.
5 Q. Who did you hear that from?
6 A. Dr. Vosskuhler, I believe.
7 Q. What did he tell you?
8 A. He showed me some polaroid photographs and
9 said that some employees of Mallinckrodt had been caught
10 disassembling one of our Polar Air units at some facility
11 somewhere.
12 Q. Did he tell you where it was?
13 A. He did, but I don't recall what he said.
14 Q. Did he tell you anything else about that
15 situation?
16 A. Not that I recall.
17 Q. Did he tell you what -- what he meant by
18 disassembling?
19 A. No, I don't think we discussed it.
20 Q. Does the -- does the Polar Bair product have a
21 evaporation tray?
22 A. I believe so.
23 Q. What does the evaporation tray do?
24 MS. SORANNO: Objection, lack of
25 foundation.

1 A. There is, as with any air conditioning unit,
2 if the humidity level in the environment where it's being
3 used gets substantial there's a certain amount of
4 condensation which collects in the -- in the heat exchanger,
5 and the evaporation tray was just a means of collecting this
6 condensation and evaporating it.
7 BY MR. KURZ:
8 Q. Was there any way of -- of checking whether
9 there was water in the evaporation tray?
10 A. I don't recall.
11 Q. Do you recall whether the evaporation tray
12 slid in and out?
13 MS. SORANNO: Objection, lack of
14 foundation.
15 A. I believe it does.
16 BY MR. KURZ:
17 Q. You believe it does. Would you think that if
18 someone slid out the evaporation tray that they would be
19 considered to be disassembling the Polar Bair product?
20 MS. SORANNO: Objection, lack of
21 foundation.
22 BY MR. KURZ:
23 Q. Would that constitute disassembling the
24 product to your knowledge?
25 MS. SORANNO: Same objection.

1 A. I couldn't say.
2 BY MR. KURZ:
3 Q. Why can't you say?
4 A. If the tray just merely slid out it wouldn't
5 seem that that would be disassembling it, I don't know.
6 Q. Did Dr. Vosskuhler tell you anything else
7 about the Washington University situation?
8 A. Not that I recall.
9 Q. Can you think of any articles that were ever
10 written about the Polar Bair product?
11 A. I don't recall.
12 Q. Have you ever seen any articles written about
13 the Polar Bair product?
14 A. I couldn't say for certain.
15 Q. Did you discuss the statements that were made
16 by Dr. Vosskuhler with anyone else?
17 A. Not that I recall.
18 Q. Have you ever heard from anyone else aside
19 from Dr. Vosskuhler that -- any allegations that Mallinckrodt
20 employees viewed a Polar Bair product?
21 A. Not that I recall specifically, no.
22 Q. What else did Dr. Vosskuhler -- Dr. Vosskuhler
23 show you aside from photographs?
24 A. I don't recall anything else.
25 Q. Did he show you any correspondence?

1 A. I don't recall.
2 Q. Was anyone else present when you talked to
3 him?
4 A. I don't recall.
5 Q. Do you know why he told you about that subject
6 matter?
7 MS. SORANNO: Objection, calls for
8 speculation.
9 A. He and I share an office, that could have
10 something to do with it.
11 BY MR. KURZ:
12 Q. Did he tell you whether he thought that the
13 Mallinckrodt employees did anything wrong?
14 A. I don't recall.
15 Q. Did you reach an understanding in your own
16 mind as to whether you thought Mallinckrodt employees did
17 anything wrong?
18 A. I don't recall.
19 Q. Do you have an opinion about that now?
20 A. I don't understand -- I haven't heard all the
21 facts in the case, I don't understand.
22 Q. Did Dr. Vosskuhler relate to you any
23 discussions he had with any other individuals regarding --
24 regarding the Mallinckrodt viewing of the Polar Bair product?
25 A. What was the question again?

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1 Q. Did Dr. Vosskuhler relay to you any
2 conversations he had with anyone else regarding Mallinckrodt
3 employees viewing the Polar Bair product?
4 A. I don't recall.
5 Q. Did you consider the -- until the first sale
6 of the Polar Bair did you consider the exterior of the
7 product to be a company trade secret?
8 MS. SORANNO: Objection to the extent it
9 calls for a legal conclusion.
10 A. I hadn't given it any thought.
11 BY MR. KURZ:
12 Q. Did you think that it was -- that the exterior
13 of the Polar Bair product was confidential in any way?
14 MS. SORANNO: Same objection.
15 A. I hadn't given it any thought.
16 BY MR. KURZ:
17 Q. Did anyone tell you to keep the Polar Bair
18 product confidential?
19 A. I wasn't involved in the product in any sense
20 that I would have occasion to.
21 Q. But did anyone ever warn you not to talk about
22 the Polar Bair product?
23 A. Not that I recall, no.
24 Q. Have you ever seen any reference to the Polar
25 Bair product being a confidential product?

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1 A. Not that I recall.
2 Q. Within Augustine was access to the Polar Bair
3 product restricted to your knowledge?
4 A. I guess no more so than any other product that
5 we work on in R & D.
6 Q. Where was the product -- was there a
7 particular location where most of the work on the Polar Bair
8 product took place?
9 A. Within the R & D area of Augustine Medical,
10 yes.
11 Q. Is that a restricted area?
12 A. Yes.
13 Q. Are there signs that indicate that it's
14 restricted?
15 A. It's key code access.
16 Q. Are there any signs that you're aware of that
17 indicate that it's restricted access?
18 A. I don't believe so.
19 Q. Who worked on the design of the Polar Bair?
20 A. The primary engineers on the project were
21 Hamid Zameer and Don Staff, they were the principals.
22 Q. Anyone else work on it to your knowledge?
23 A. Other people had a hand in it from time to
24 time, but they were the principals.
25 Q. Can you think of who else had a hand in it?

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1 A. Well, I worked on it for a little bit, Greg
2 Hamlin might have at some point.
3 Q. What does Greg Hamlin do?
4 A. He's a engineer with R & D.
5 Q. Anyone else you can think of?
6 A. Tom Anderson might have on occasion.
7 Q. Anyone else?
8 A. Dr. Augustine was certainly there as a advisor
9 and supervisor of the project.
10 Q. Do you ever recall any labeling on the Polar
11 Bair product that indicated that it was confidential?
12 A. I don't recall.
13 Q. You don't recall seeing any confidential
14 stickers or anything like that?
15 A. I do not.
16 Q. Aside from the R & D area that you described
17 was the Polar Bair product ever located even temporarily
18 anywhere else within Augustine?
19 MS. SORANNO: Objection, lack of
20 foundation, calls for speculation.
21 A. I don't recall.
22 MR. KURZ: Counsel, why would you say it
23 would be speculation for me to ask the witness whether he
24 knew whether the product was located in anyplace other than
25 the R & D department?

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1 MS. SORANNO: Because he did not have
2 involvement with the entire project. He said he was involved
3 from time to time. And you have not laid the foundation that
4 he knew the whereabouts of the Polar Bair throughout the
5 entire existence of the project.
6 MR. KURZ: Well, knowing the whereabouts
7 of the product during the entire development process is a
8 different question than knowing whether he's ever seen it or
9 was aware of it anyplace other than the R & D department.
10 And I would ask you to refrain from unnecessary objections.
11 MS. SORANNO: My objection stands. I'm
12 not withdrawing my objection.
13 MR. KURZ: Okay, and I'm going to ask you
14 in the future to refrain from that as -- I'll just leave it
15 at that for the time being.
16 MS. SORANNO: That's fine.
17 MR. KURZ: And ask you to refrain from
18 unnecessary objections.
19 MS. SORANNO: Your objection is noted.
20 BY MR. KURZ:
21 Q. I want you to think carefully and think
22 whether you can recall ever seeing the Polar Bair unit
23 anyplace other than the R & D department?
24 MS. SORANNO: Objection, asked and
25 answered.

1 A. I just don't recall.
 2 BY MR. KURZ:
 3 Q. Have you ever seen it anyplace outside of
 4 Augustine?
 5 A. I've seen it in transport.
 6 Q. When did you first see it in transport?
 7 A. I don't recall specifically.
 8 Q. Where did you see it in transport?
 9 A. We worked with a couple of outside firms in
 10 the development of -- of manufacture and R & D effort, and
 11 from time to time the chief engineers had occasion to
 12 transport the machines to other sites.
 13 Q. Who are these outside vendors?
 14 A. I don't recall specifically.
 15 Q. You don't recall any of them?
 16 A. No.
 17 Q. How would the product be transported?
 18 A. Put in the back of a van.
 19 Q. An Augustine van?
 20 A. An Augustine van or an employee van.
 21 Q. When you recall seeing it transported do you
 22 remember who was driving the van?
 23 A. I can think of occasions when Hamid
 24 transported it.
 25 Q. Anyone else?

1 A. Not that I recall.
 2 Q. Were you with him when he transported it?
 3 A. No.
 4 Q. Did you help him load it on?
 5 A. I don't recall.
 6 Q. You just remember seeing it being loaded on to
 7 a van?
 8 A. Yes.
 9 Q. On how many occasions?
 10 A. Several.
 11 Q. And this is during the -- the development
 12 stage of the Polar Bair?
 13 A. Yes.
 14 Q. Was there anyone with you when you saw the
 15 Polar Bair being loaded on to a van?
 16 A. I don't recall.
 17 Q. Have you had any discussions with anyone after
 18 Dr. Vosskuhler talked to you regarding the issue of whether
 19 the Polar Bair product was or was not confidential?
 20 A. Not that I recall.
 21 Q. When was your first awareness of Mallinckrodt
 22 as a company do you recall?
 23 A. I think probably when I initially started at
 24 the company, shortly thereafter.
 25 Q. Was anything said to you regarding

1 Mallinckrodt shortly after you started with the company?
 2 A. I think probably my first recollection was
 3 Scott telling me at one point that Mallinckrodt had taken an
 4 interest in our company and had come up to the Twin Cities
 5 for a visit.
 6 Q. Did that visit occur while you were at
 7 Augustine or prior to that?
 8 A. Prior to it, I believe.
 9 Q. What did he tell you about Mallinckrodt's
 10 interest in the -- in the product?
 11 A. I don't recall.
 12 Q. Did he -- did there come a time when he told
 13 you that Mallinckrodt no longer had an interest in the
 14 product?
 15 A. I don't recall.
 16 Q. What else did he tell you about Mallinckrodt?
 17 A. I don't recall.
 18 Q. How many occasions did he talk to you about
 19 Mallinckrodt's interest in any products of Augustine's?
 20 A. I don't recall.
 21 Q. Was it more than once?
 22 A. It might have been, I don't remember.
 23 MR. KURZ: Okay, why don't we take a short
 24 break.
 25 VIDEO TECHNICIAN: Going off video record.

1 (Whereupon, a brief recess was taken
 2 from 2:35 to 2:45.)
 3 VIDEO TECHNICIAN: Continuing with video
 4 record.
 5 MR. KURZ: Okay, I just wanted to say that
 6 I had no more questions for you today. Thank you very much
 7 for your time. I also wanted to ask counsel if in addition
 8 to bringing in the polaroids of -- the originals of the
 9 polaroids of the Washington University matter whether you
 10 could also bring with you tomorrow, whoever comes to the
 11 deposition tomorrow brings a sample of the blanket with the
 12 hose inlet that Mr. Arnold drew in Exhibit Number 5.
 13 MS. SORANNO: We will bring the upper body
 14 blanket that you referenced in Exhibit Number 5, and if we
 15 have the polaroids, we're checking, we will -- we will
 16 produce them.
 17 MR. KURZ: Okay, thank you.
 18 VIDEO TECHNICIAN: This is the end of the
 19 video record.
 20 MS. SORANNO: Oh, Mr. Arnold, you have the
 21 right to review your deposition transcript once it has been
 22 transcribed. And I would recommend that you exercise that
 23 right.
 24 THE WITNESS: Okay.
 25 (Whereupon, at 2:48 p.m. on Tuesday,

February 27, 1996, the taking of the deposition
of RANDY ARNOLD was concluded.)

STATE OF MINNESOTA)
COUNTY OF HENNEPIN) ss.

Be it known that I took the deposition of RANDY
ARNOLD, on the 27th day of February, 1996, at 3400 IDS
Center, Minneapolis, Minnesota;

That I was then and there a Notary Public in and for
the County of Hennepin, State of Minnesota, and that by
virtue thereof I was duly authorized to administer an oath;

That the witness before testifying was by me (me)
duly sworn to testify the whole truth and nothing but the
truth relative to said cause;

That the testimony of said witness was recorded in
Stenotype by myself and transcribed into typewriting under my
direction; and that the deposition is a true record of the
testimony given by the witness to the best of my ability;

That I am not related to nor interested in the outcome
of the action;

That the cost of the original transcript has been
charged to the party availing the deposition, unless
otherwise agreed upon by Counsel, and that copies have been
made available to all parties at the same cost, unless
otherwise agreed upon by Counsel;

That the reading and signing of the deposition by the
witness was executed as evidenced by the preceding pages;

That Notice of Filing was waived.

WITNESS MY HAND AND SEAL this 11th day of March,
1996.

Jennifer A. Scharf
Court Reporter

(Upon completion, the Original of this Reading and Signing
Certificate should be forwarded to the Attorney availing the
Deposition.)

(RANDY ARNOLD: CONFIDENTIAL PORTION)

I, Randy Arnold, do hereby certify that I have read
the foregoing transcript of my Deposition and believe the
same to be true and correct (or, except as follows, stating
the page and line number of the change or addition desired
and reason why):

Page Line Change or Addition Reason

Signed:

Dated this day of , 1996.

(L.A.B.)



RANDY ARNOLD

Condenselt™

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RANDY ARNOLD

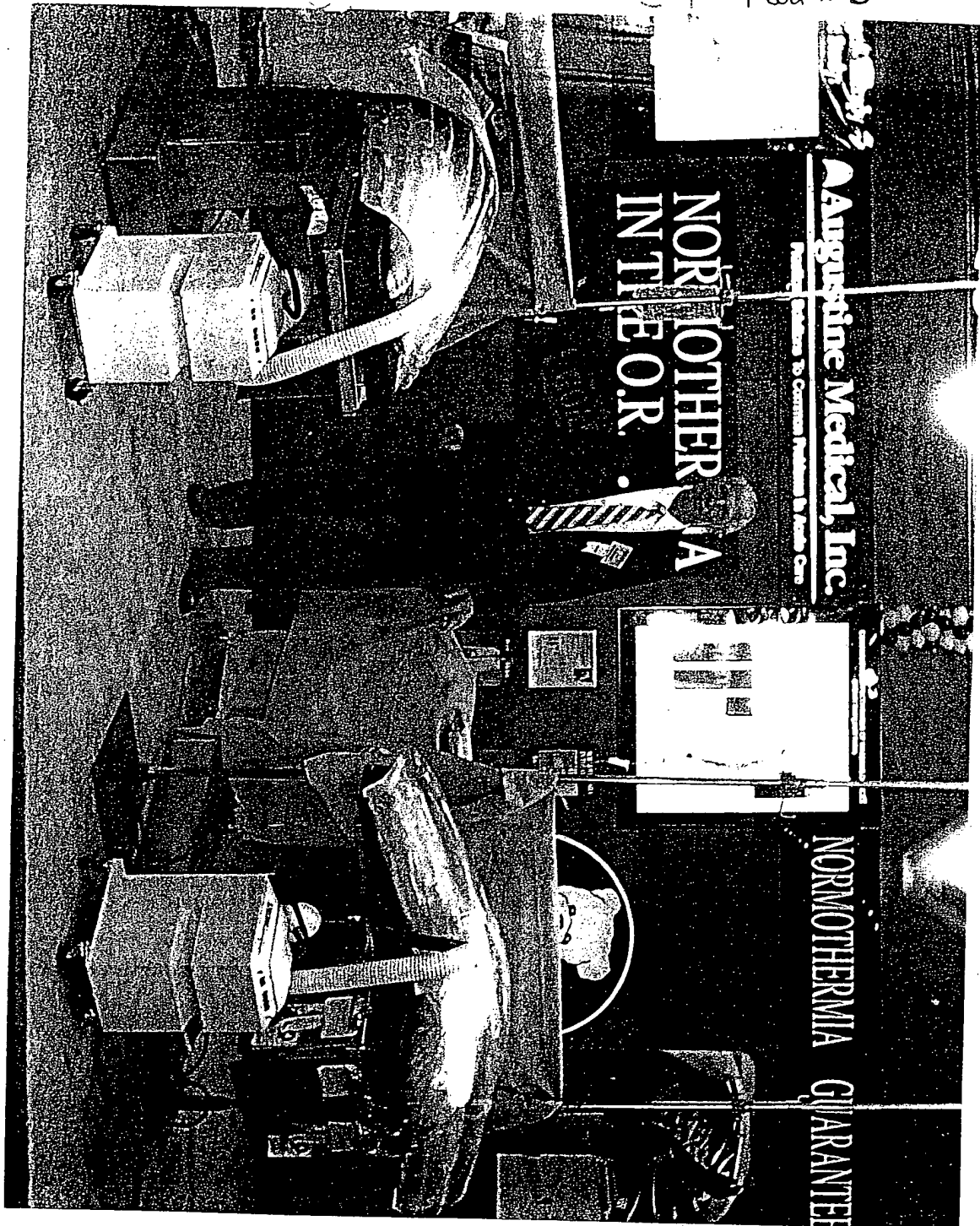
Condenset™

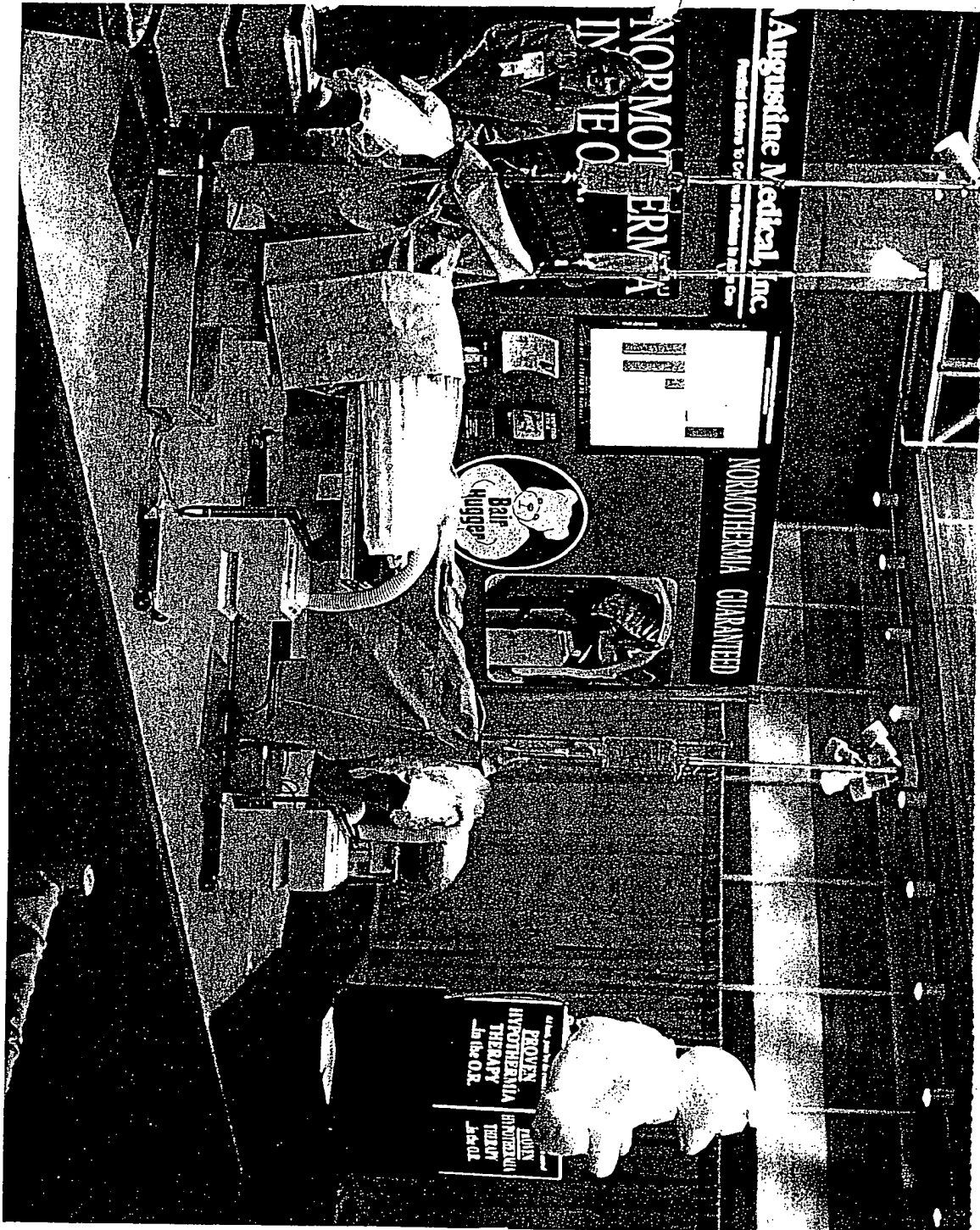
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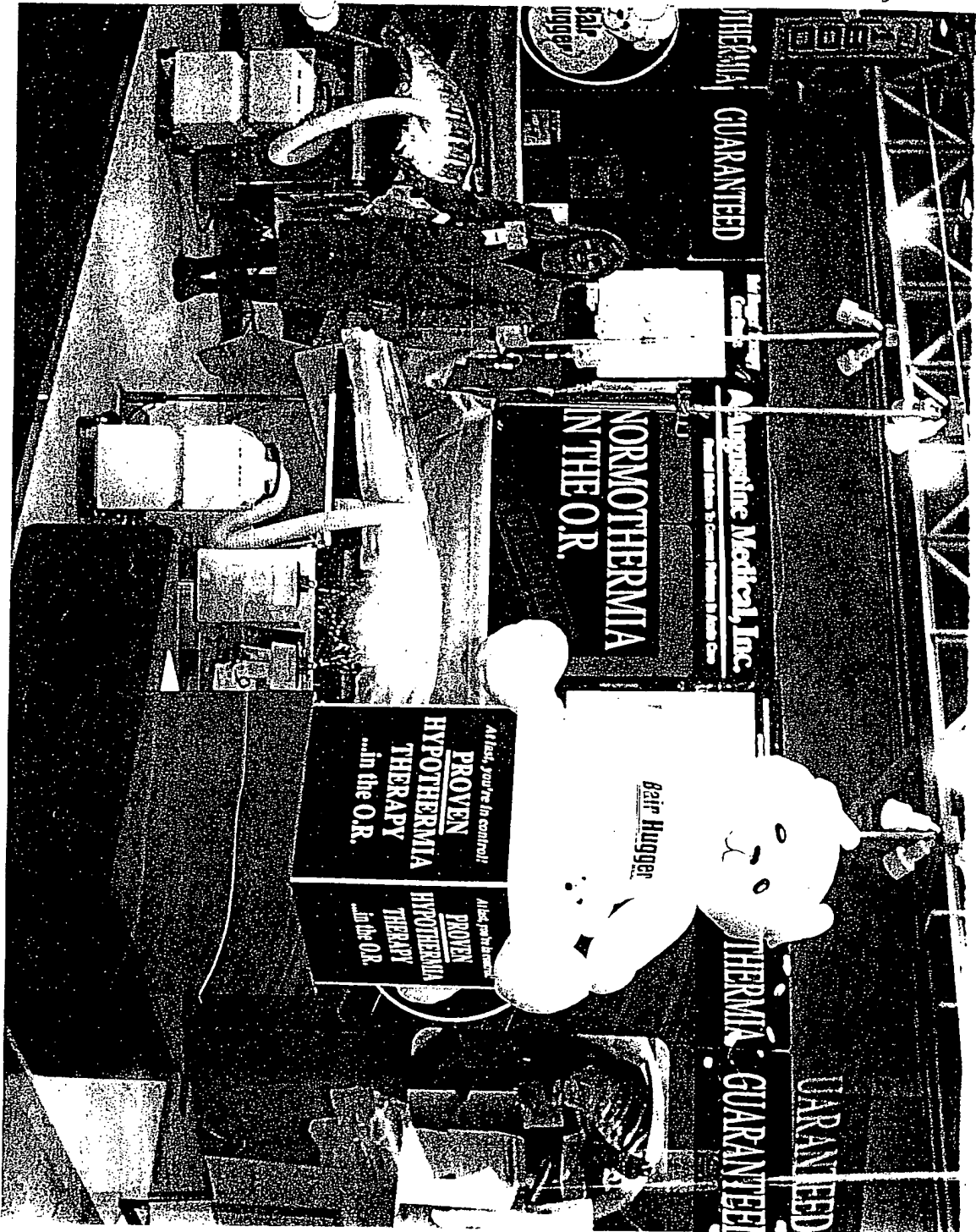
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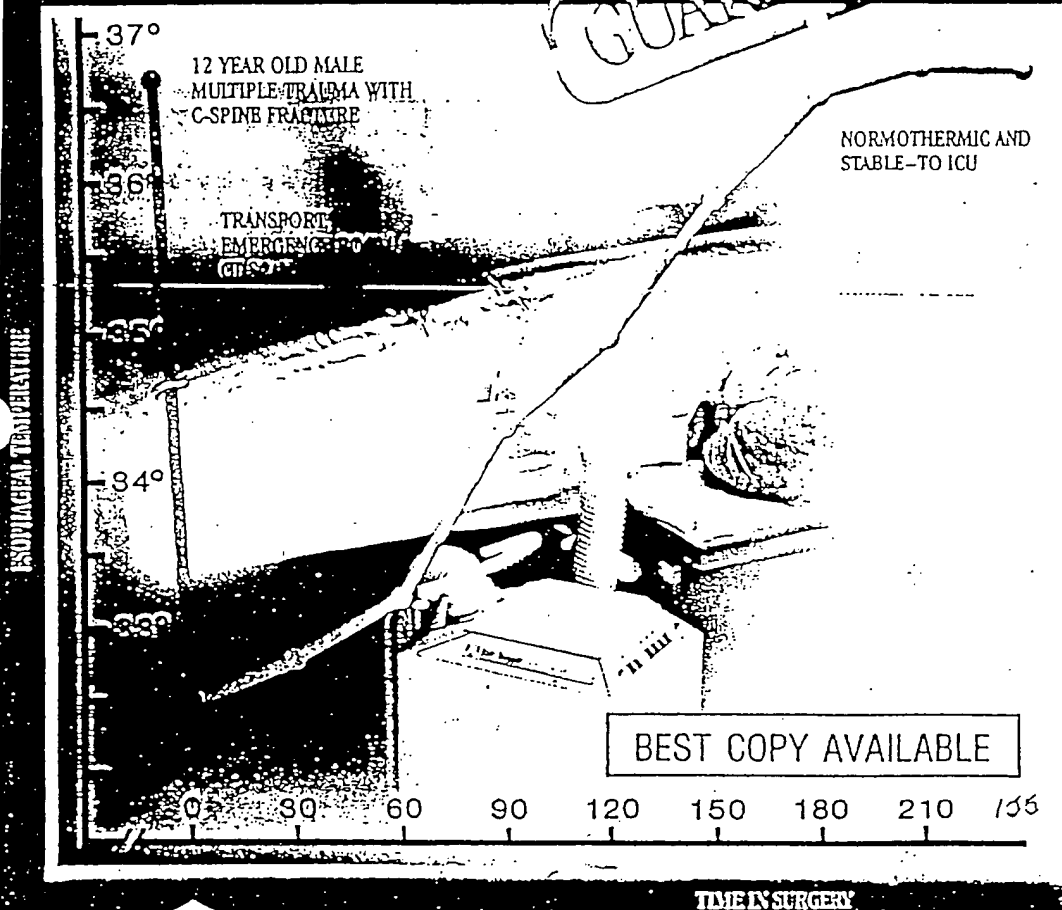




AUGUSTINE MEDICAL INTRODUCES...

NORMOTHERMIA IN THE O.R.

GUARANTEED



**BAIR HUGGER™
CONVECTIVE WARMING
THERAPY™ STARTED IN O.R.**

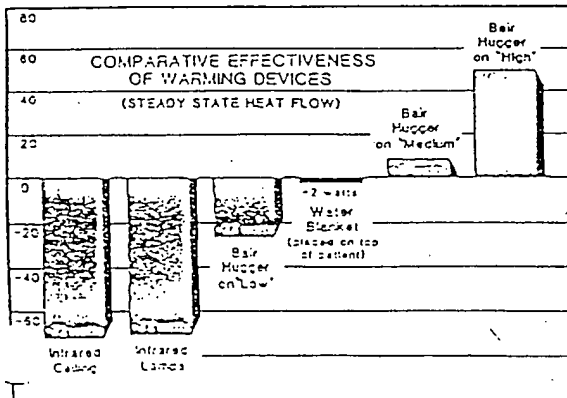
DOCUMENT E

AT LAST, YOU'RE IN CONTROL!

Augustine Medical *guarantees* that Bair Hugger™ Convective Warming Therapy™ will maintain normothermia in the O.R. Far too many patients become seriously hypothermic despite the physician's best efforts. In fact, studies show that 60%-80% of all O.R. patients are hypothermic when treated with the traditional "warming" devices, which are virtually ineffective.™ Bair Hugger Convective Warming Therapy™ has *actively* warmed over 150,000 hypothermic PACU patients in its first year of use. Its effectiveness has been documented in several clinical studies.™ The proven effectiveness of Bair Hugger Therapy establishes a new standard of care. With Bair Hugger Convective Warming Therapy, hypothermia in the O.R. is a problem of the past, *guaranteed!*™

Bair Hugger™ Convective Warming Therapy™ is the Only Proven Method of Active Surface Warming.

All of the available methods of surface warming were tested for effectiveness at the University of California-San Francisco. Using heat flux transducers in a controlled laboratory setting, Dr. Dan Sessler found that only Bair Hugger Therapy actively transfers heat to the patient. "… (Bair Hugger Therapy) provided enough heat to increase body temperature almost 3°C per hour."™ The other technologies did not transfer heat to the patient and in fact could not even prevent the patients from losing their endogenous heat.²



"The Bair Hugger™ is the first device that allows you to choose your patient's temperature and keep them there. We've had control of blood pressure and pulse for years, now we can finally control temperature."

Neil Feinglass, M.D., Jacksonville, FL

"Bair Hugger: Body Heat"

— JAMA
— ANESTH
— ASA



Bair Hugger



its Loss of
ress release,
Orleans, LA, 1989

"The injured patient arrived in the O.R. cold and bradycardic. Active warming with the Bair Hugger™ resulted in a rapid improvement of the temperature and stabilization of the heart rate."

—K.G. Belani, M.D., Minneapolis, MN

CONVECTIVE WARMING THERAPY™



Bair Hugger™ Warming Covers are Available in Two Styles

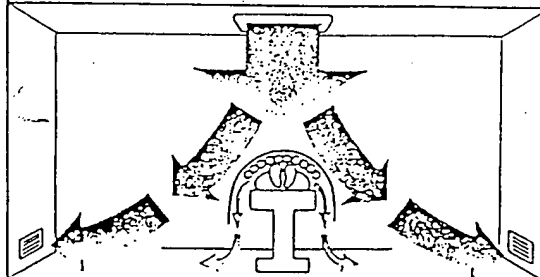
A chest/arm Cover for abdominal and lower extremity operations and a leg Cover for abdominal, thoracic and intracranial operations.

Localized Air Flow

The combination of the Steridrape™ (3M, St. Paul, MN) barrier design and the overlying surgical drape, prevents the warm exhaust air from migrating toward the surgical incision. The heated air flows from under the surgical drape toward the floor. It is then carried directly toward the room exhaust vents by the large volume of room ventilation air which is blowing directly down on the patient from the ceiling.

The warm air contributes less than 3% of the total air circulation in the O.R. and is undetectable at the surgical site. Bair Hugger air is filtered through a 0.2 micron filter before heating.

O.R. AIRFLOW IN THE OPERATING ROOM
AIRFLOW: 1,300 - 26,000 CU.FT./MINUTE
VELOCITY: 20 - 200 LIN.FT./MINUTE



BAIR HUGGER™ AIRFLOW: 35 CU.FT./MINUTE
VELOCITY: 3 LIN.FT./MINUTE

(AIRFLOW IN TOTAL AIRFLOW DIRECTED AWAY FROM THE INCISION)



Bair Hugger™ Convective Warming Therapy is:

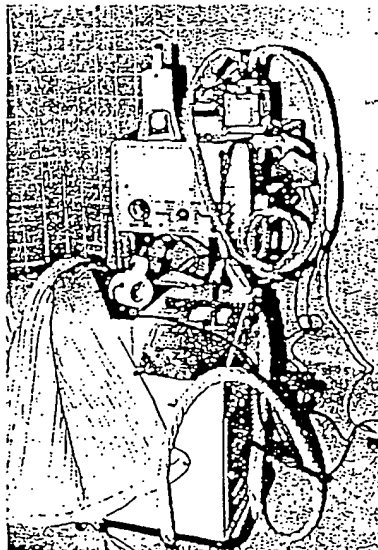
Safe Convective Warming is as safe as turning up the room temperature. In contrast, water based warming technologies such as water mattresses and heated humidifiers have caused numerous cases of full thickness burns and tracheal injury.⁽¹⁾

Convenient The Bair Hugger Warming System can also warm I.V. fluids and blood! Up to one liter/hour of room temperature fluid can be warmed by simply adding two lengths of extension tubing to the I.V. line and placing them between the warm air tubes of the Cover.

Up to three liters/hour of cold blood can be warmed with a Bair Hugger™ Fluid Warming Cassette which is inserted into the center air tube. Traditional fluid warmers allow the fluid to cool during the six foot transit to the patient. The Bair Hugger System keeps the fluid warm right up to the I.V. site. Bair Hugger fluid warming is inexpensive, efficient and reduces equipment needs.

Cost Effective Our simple and safe warming therapy eliminates any need for water mattresses and airway heaters. For humidification of the tracheal mucosa, we do recommend the use of an "artificial nose" (airway Heat and Moisture Exchanger). The Bair Hugger fluid warming capability makes blood/fluid warmers unnecessary in all but the very large volume resuscitations.

Practical Bair Hugger Convective Warming Therapy consists of a Heating Unit and a disposable Warming Cover that directs a gentle flow of warm air across the patient's body which provides for



Bair Hugger™ Therapy allows you the freedom to concentrate on the patient, not on the equipment!

safe and effective warming. The Bair Hugger Heating Unit uses a reliable, high efficiency blower, a sealed 850 Watt heating element, and a microprocessor based temperature controller to create a continuous flow of warm air. The patented Warming Cover is made of a layer of plastic and a layer of tissue paper/plastic laminate, bonded together into long tubular channels. When inflated, the self-supporting Warming Cover is designed to arch over the patient's body, creating a warm "cocoon". The warm air exits through microperforations in the Cover's underlayer, resulting in convective warming as it surrounds the patient.

Free Trial If you are interested in effective, safe and convenient patient warming, a free trial of Bair Hugger Convective Warming Therapy can quickly be arranged. Just call us toll free at:

1-800-733-7775
or (612) 941-8866

***Terms of guarantee:**

1. Bair Hugger™ Convective Warming Therapy™ must begin immediately after induction of anesthesia on the "high" setting and continue throughout the case if indicated.
 2. Infused blood and fluids must be warmed to body temperature.
- If these two criteria are met and the patient is hypothermic at the end of the operation (core temperature 36°C), Augustine Medical will replace the Warming Cover. This guarantee is limited to the replacement of the Warming Cover.

SPECIFICATIONS HEAT/BLOWER UNIT

Size:	23" high x 16" deep x 14" wide
Weight:	32 lbs
Power Requirements:	110 VAC
Temperature Range:	Ambient to 110°F Max
Enclosure:	Enamelled Steel
Power Cable:	14 Feet Long
Filter:	High efficiency 0.2 air filter
Covers	
Arm Cover Size:	82" x 20"
Leg Cover Size:	32" x 36"
Weight:	6 ounces
Material:	Polyethylene and tissue paper laminate



AUGUSTINE MEDICAL INC.

PRACTICAL SOLUTIONS TO COMMON PROBLEMS IN ACUTE CARE™

10393 West 70th Street • Eden Prairie, Minnesota 55344
Phone: 1-800-733-7775

BEST COPY AVAILABLE

(1) Vaughn MM, et al: Anesth Analg 60:746-751, 1981. (2) Sessler O, et al: Oral Presentation American Society of Anesthesiologists Annual Meeting, New Orleans, LA 1989 (in Press). (3) Morris RH, et al: Anesthesiology 58:406-411, 1972. (4) Cohen ML, et al: Aviation, Space & Environmental Medicine 43:225-232, 1972. (5) Sessler O, et al: Anesthesiology 71:1112-1114, 1989. (6) Cooper MA, et al: ASA 88:559, 1988. (7) Craschoun SB, et al: Poster presentation, ACPA National Congress, Anaheim, CA, Feb. 1989. (8) Sessler O, et al: In Press 1989. (9) Bair Hugger™: Prevention Loss of Body Heat: American Society of Anesthesiologists, Press release, ASA Annual Meeting, New Orleans, LA, Oct 1989. (10) Scott AM, et al: Surg 54:275, 1962. (11) Cunn MM, et al: Anesthesiology 29:149-150, 1958. (12) Sims MM, et al: Anesthesiology 65:4450, 1986. (13) Kern EF, et al: Chest 55:225-226, 1974. (14) Stowman WS, et al: JAMA 254:1111-1112, 1985.

*** CONFIDENTIAL - FILED UNDER SEAL ***

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Fourth Division

AUGUSTINE MEDICAL, INC.,

Plaintiff,

v.

MALLINCKRODT GROUP, INC. and
MALLINCKRODT MEDICAL, INC.,

Defendants.

Civil Action No. 4-94-CV-875

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION
FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT

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JUNE 23, 1995

DOCUMENT F

AMT's Thermal Blankets Do Not Infringe The '102, '320 Or '371 Patents

The three remaining asserted patents, namely, the '102, '320 and '371 Patents, are all directed to improvements to AMT's self-erecting thermal blanket. (See Lynch Decl., Exhibit D for the genealogy of these three patents.) All asserted claims of the '102, '320 and '371 Patents require the "self-erecting" feature. The Summary of the Invention portions of the specifications of the '102, '320 and '371 Patents all begin with the statement that "we have improved the clinical usefulness of the self-erecting airflow cover." See Lynch Decl., Exhibits A-2, A-3 and A-4.

Importantly, each of the patent specifications contains a clear definition of what is meant by "thermal blanket":

"thermal blanket" is meant to invoke a self-erecting, inflatable structure for delivering a thermally-controlled inflating medium to the interior of the structure created when the thermal blanket is inflated.

See Lynch Decl., Exhibit A-2, column 3, lines 30-35; A-3, column 3, lines 3-7; and A-4, column 4, lines 1-4. Here, the patent specifications of the patents-in-suit perform the precise function which specifications may perform as noted by the Federal Circuit in Markman, namely, "for claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims." 52 F.3d at 979.⁹

The '102, '320, and '371 Patents describe the "self-erecting" feature as follows:

When the blanket is inflated, it erects itself into a Quonset hut-like structure with a quilted upper surface.¹⁰

⁹ Although the term "self-erecting" or the similar phrase "inflatably erected" appear in nearly all of the asserted claims of these three patents, in claims such as Claim 1 of the '102 Patent, which merely refers to a "thermal blanket," AMT has admitted, as it must, that reference to "thermal blanket" is in fact a reference to the self-erecting "thermal blanket." See Lynch Decl., Exhibit G, pp. 428, lines 5-10. This is consistent with the definition of "thermal blanket" contained in the specification of each of the patents-in-suit as discussed above.

¹⁰ "Quonset" is defined in *Webster's Third New International Dictionary* as a trademark "used for a prefabricated shelter set on a foundation of bored steel trusses and built of a semicircular arching roof of corrugated metal insulated with wood fiber." (Emphasis added.)

Lynch Decl., Exhibit A-2, column 3, lines 48-50; A-3, column 3, lines 20-22, and A-4, column 4, lines 17-19. Seemingly, there should be no controversy as to the meaning of "self-erecting" based on the clear description in the specifications of the '102, '320, and '371 Patents. Nevertheless, although AMI concedes that the term "thermal blankets" in the asserted patents means "self-erecting," AMI's position regarding this essential element is otherwise similar to the position it has taken with respect to the '188 Patent. That is, AMI advocates ignoring the clear wording of the patents as well as the prosecution histories thereof, such that "self-erecting" does not mean "self-erecting." Specifically, AMI's apparent position is that "self-erecting" means the mere expansion of the blanket ("it assumes a volume") upon being inflated with air. See, e.g., Lynch Decl., Exhibit G, p. 431, lines 23-24. According to AMI, "self-erecting" does not mean the formation of a curved or arched structure around or about the patient. See Lynch Decl., Exhibit G, p. 429, line 17 - p. 434, line 22.

AMI's position is at odds with the unequivocal language in the specification of each patent which explains that when the blanket is inflated it erects itself into a Quonset hut-like structure. Other references throughout the patents confirm the fact that prior to the litigation, AMI meant "self-erecting" to designate a blanket formed (i.e., erected) into a curved or arched (Quonset hut-like) structure over or about a patient. See, e.g., Figures 1 and 2 of the '188 Patent (Lynch Decl., Exhibit A-1) and column 2, lines 9-13 of the '102 Patent (Lynch Decl., Exhibit A-2) which states, "when inflated and erected over a patient, [the thermal blanket] delivers the thermally-controlled inflating medium into the interior of the structure covering the patient." Elsewhere, the '102 Patent states, "[a]s illustrated in FIG. 1, the thermal blanket of the invention is inflated, erects itself into a bathing structure and bathes a patient 26 with the thermally-controlled air used to inflate the structure." Lynch Decl., Exhibit A-2, column 4, lines 1-4.

The '320 Patent specification contains additional similar language, namely, "[w]ith these improvements, the thermal blanket, when inflated and erected over a patient . . .," Lynch Decl.,

Exhibit A-3, column 2, lines 1-5, as does the specification of the '371 Patent ("The purpose of the thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within the erected structure,") Lynch Decl., Exhibit A-4, column 4, lines 4-7 (emphasis added)). Additionally, the '371 Patent Abstract states, "When inflated, the thermal blanket self-erects and provides a bath of thermally-controlled medium to the interior of the erected structure" Lynch Decl., Exhibit A-4 (emphasis added). The '320 Patent states:

An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering into the structure created when the cover self-erects upon inflation.

Lynch Decl., Exhibit A-3, column 1, lines 58-61 (emphasis added).

Even when faced with examples such as these during his deposition, Dr. Augustine continued to insist that self-erecting does not mean forming a structure about or erected around the patient. Rather, Dr. Augustine maintained his litigation position that "self-erecting" only means inflating and becoming three-dimensional. See Lynch Decl., Exhibit G, p. 434, line 13 - 22. Dr. Augustine insisted that the subject matter of the asserted patents did not contemplate a blanket that erected into a structure that stood off of a person or erected about or around a person. See, e.g., Lynch Decl., Exhibit G, pp. 429, lines 4-19 and 441, lines 6-14. Instead, Dr. Augustine maintained that the Quonset hut-like structure of the patents-in-suit was formed only if the blanket was "self-erected" (i.e., inflated) over a patient, i.e., a patient is required to form the blanket into the Quonset hut. See Lynch Decl., Exhibit G, p. 437, lines 6-7. The prosecution histories of the subject patents show that this position is spurious.

For example, when arguing to the PTO that the claimed subject matter of the '102 Patent was patentably distinct from the inflatable blanket disclosed in U.S. Patent No. 4,660,388 to Greene, Jr. (the "Greene Patent," Lynch Decl., Exhibit B-4), AMI argued:

Greene failed to make two critical observations which characterize the air flow cover and its progeny and which differentiate that class of thermal blankets from the class of covers embodied in Greene. First, Greene failed to realize that the transverse plenums stiffen an inflatable pad and maintain it in an essentially planar structure which is altogether

unsuitable for "forming an enclosure" when inflated. In contrast, the airflow cover of the '188 patent and the thermal blanket described and claimed in this application do not employ transverse plenums, but, rather, communicate air between inflatable chambers by a multitude of transverse openings between the chambers. This permits the thermal blanket to assume the shape of a curved surface which curls downwardly toward its edges from its center and forms a quonset-type structure.

Lynch Decl., Exhibit C-2 (Application Serial No. 887,233) at pp. 7-8 (emphasis added).

Elsewhere, in attempting to convince the PTO that the claims of the '102 Patent were patentably distinct from the Greene Patent (as well as the patent issued to Kliesrath, U.S. Patent No.

2,110,022, Lynch Decl., Exhibit B-1), AMI argued:

In contrast [to Greene and Kliesrath], the air flow cover of the '188 patent and the thermal blanket described and claimed in this application consist entirely of:

an inflatable structure with a plurality of mutually-communicating inflatable chambers which erects into an enclosure to enclose a person;

Id. at p. 8-9 (emphasis added). AMI further stated:

Manifestly, the airflow cover of the '188 and thermal blanket of this application are significantly different than the covers of Greene and Kliesrath. They self-erect and, in doing so, eliminate the need for a non-inflating coverlet or quilt.

Id. at p. 9 (emphasis added). AMI then concluded:

Therefore, the thermal blanket disclosed and claimed in this application is different from the device disclosed by Greene because it self-erects and does not include a non-inflatable cover and means for receiving a pad, the pad alone being inflatable.

Id. (emphasis added).

During prosecution of the '320 Patent, AMI made virtually identical arguments. See '320 Patent file history (Application Serial No. 703,592), Lynch Decl., Exhibit C-3 at 13-15.

Additional similar arguments were made in the application which was the parent application to the '320 Patent and the grandparent application to the '371 and '102 Patents (Application Serial No. 227,189, Lynch Decl., Exhibit C-4). During the prosecution of the 227,189 application which eventually matured into the '102, '320 and '371 Patents, Applicants were attempting to distinguish the type of thermal blankets which were the subject of that application by

differentiating between convective thermal blankets (as in the application) and blankets which come in contact with the body (so-called "conductive" blankets). Applicants argued:

Evidently, the Examiner was under the impression that the airflow cover and the convective thermal blanket of this application operate by contacting a patient. If this were true, a much stronger relationship to the Bailey structure could be argued. However, as the applicants' representative stated, and as the enclosed photographs show, "[t]he airflow cover and the convective thermal blanket, when inflated, stand off of a patient. This is vital to the blanket's operation, since contact with the patient would block passage of the inflating medium through the occluded apertures in the undersurface and would prevent the blanket from bathing the patient in an inflating medium."

Thus, while use of Bailey's conductive thermal blanket requires that it contact a person, such contact impedes correct operation of the convective thermal blanket of this application.

Lynch Decl., Exhibit C-4, pp. 3-4 (first emphasis original, second emphasis added.)

The Applicant later continued:

All of the new claims are drawn to a self-erecting inflatable thermal blanket which bathes a person in a thermally controlled inflating medium. Such a thermal blanket is one which, when inflated, erects about a person standing off a person to exhaust the inflating medium which thereby bathes the person in the medium.

Id. at 4 (emphasis added).

There simply can be no doubt, based on a review of the prosecution histories and the patent specifications, that contrary to Dr. Augustine's position, *ante litem motam*, "self-erecting" does not mean merely "inflated" and reference to a "Quonset hut" structure does not mean the shape that the blanket of the asserted patents assumes only if placed on a person. As argued to the PTO by AMI, "self-erecting" means that the blanket forms a structure (like a Quonset hut) which stands off a patient. Dr. Augustine's deposition testimony must be considered to be the mere litigation posturing that it is, especially when contrasted with the pre-litigation statements made during the time that the subject patents were being prosecuted and when compared to the very language of the patents themselves.

¹¹The photographs vividly show what Applicant meant by a "self-erecting" blanket. Copies of the photographs appearing in the file history are attached to the Lynch Declaration as Exhibit C-6.

As is apparent from the photograph and drawings of the MMI blankets attached to the Virag Declaration, Composite Exhibits 1 and 2, and as described in the Virag Declaration (and as can be readily seen from a physical inspection of MMI's blankets), the accused MMI blankets do not self-erect or create a structure that arches or erects over or about the patient to stand off of the patient. To the contrary, although MMI's blankets are inflated, when inflated, they lie flat or otherwise readily conform to the shape of the person or object they cover, like a conventional blanket. Even Dr. Augustine admitted that MMI's blankets essentially take the shape of whatever they are draped over (also asserting that if placed on a patient, they "somewhat assume an arch shape"). See Lynch Decl., Exhibit G, p. 359, line 1 to p. 360, line 8. In fact, Dr. Augustine admitted that MMI's blankets are "archable" but are not "self-arching." Id. at p. 360, lines 2-3. Dr. Augustine also admitted that the presence of more material (described by Dr. Augustine as "redundant" material) on the underside of the blanket (as in MMI's blankets) impedes the blanket from arching. See Lynch Decl., Exhibit G, p. 315, line 6 - p. 316, line 7.

Significantly, even AMI's own pre-litigation Sales Training literature characterizes AMI's thermal blankets as having a "Patented arched design" and points out that MMI's blankets have "No arch design." See Lynch Decl., Exhibit F. During Dr. Augustine's deposition, he disavowed any knowledge of the AMI Sales Training literature and disagreed with the characterization contained therein, stating that the patented arch design "was written by the sales department" and "is not part of our patent." Lynch Decl., Exhibit G, p. 357, lines 14-21. Prior to being faced with the AMI Sales Training literature, Dr. Augustine testified during his deposition that the patented arch design was part of an AMI patent. Lynch Decl., Exhibit G, p. 289, lines 14-23.

It is the Court's province to interpret the subject claims as a matter of law. That interpretation leads inescapably to the conclusion that the self-erecting requirement of each of the claims of the '102, '320, and '371 Patents means the self-formation of a curved structure about, around or over the patient which stands off of the patient. Based on AMI's own

admissions, as well as the empirical viewing of MMI's blankets, it is clear that MMI's blankets do not embody this critical element of all of the asserted claims and therefore cannot infringe any of the asserted claims of the '102, '320 or '371 Patents.¹²

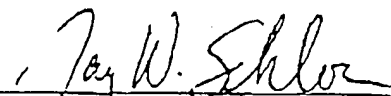
CONCLUSION

For the foregoing reasons, it is apparent that MMI's thermal blankets do not infringe any of the asserted claims of the patents-in-suit and MMI's motion for summary judgment of non-infringement should therefore be granted.

DATED: June 23, 1995

BRIGGS AND MORGAN

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MALLINCKRODT GROUP INC. AND
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¹²Again, given the fundamental differences in construction between MMI's blankets as compared to the requirements of the asserted claims of the '102, '320 and '371 Patents, no viable claim can be made that the asserted claims of the '102, '320 and '371 Patents are infringed under the doctrine of equivalents as MMI's blankets do not perform substantially the same function, in substantially the same way, to achieve the same result, and the patents cannot be extended in contravention of the principle of prosecution history estoppel.

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION

Augustine Medical, Inc.,

CV: 4-94-875

Plaintiff,

REPORT AND RECOMMENDATION

v.

Mallinckrodt Group Inc. and
Mallinckrodt Medical, Inc.,

Defendants.

J. Randall Benham, Esq. for Plaintiff.

Jeffery J. Keyes, Esq. and Raymond A. Kurz, Esq., for
Defendants.

THIS MATTER came before the undersigned United States Magistrate Judge on July 26, 1996, for a hearing on defendants' motion for partial summary judgment in which they seek a declaration of invalidity as to claims 1, 3, 4 and 8 of Plaintiff's U.S. Patent No. 5,405,371.

I. INTRODUCTION

In a previous Report and Recommendation, dated March 18, 1996, the court summarized the general dispute between the parties and the facts related to their dispute.

The present dispute between the parties is whether claims 1, 3, 4 and 8 of AMI's '371 patent are valid. MMI argues that these

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claims are invalid because AMI displayed, sold and distributed a written description of the device covered by claims 1, 3, 4 and 8 over a year before the effective filing date of these claims, and they are therefore precluded from patent protection. See MMI's Memo at 15-16 (citing 35 U.S.C. §102(b)). AMI argues that claims 1, 3, 4 and 8 of the '371 patent were sufficiently described in the parent application such that a person skilled in the art could have made and used the device contemplated by these claims. Under the patent code therefore, AMI argues that these four claims are entitled to a filing date of July 10, 1990, which is the filing date of the parent of the application that became the '371 patent. If AMI is correct, it is of no consequence that AMI sold or displayed the device in October 1989, only nine months before the parent application was filed. More generally, AMI argues that the parent application, which is a full body blanket, contained sufficient specifications to enable a person skilled in the art to make the blankets described in the disputed claims of the '371 patent which cover only a portion of a human body such as the legs or arms.

II. FINDINGS OF FACT

A. AMI's Patent Applications Related to the '371 Patent

The application for what became the '371 patent was filed on

January 8, 1991. It was a "continuation-in-part" application based upon a then pending application which had been filed on July 10, 1990. A copy of this application is found at Exhibit A to the Affidavit of Craig J. Lervick, and the January 8, 1991 application which resulted in the issuance of the '371 patent is found at Exhibit B. The '371 patent was issued as U.S. Patent No. 5,405,371, on April 11, 1995.¹

There is little evidence in the record beyond the text of the two patent applications. AMI's Memorandum in Opposition to Partial Summary Judgment summarizes the differences between the two applications. See AMI's Memo at 11 (citing Lervick Aff. at Exs. A and B).

In addition to textual differences, AMI relies upon an expert affidavit in which the expert opines that the application that resulted in the '371 patent was sufficiently disclosed in the parent application to entitle the application for the '371 patent to the

¹The United States Patent and Trademark Office ("PTO") assigns a number to each patent application it receives and to each patent it issues. Because the number of patent applications exceeds the number of patents issued by the PTO, there is no correspondence between the number assigned to a patent application and the number ultimately assigned to the patent which issues from that application. The January, 1991 CIP Application was assigned Application No. 638,748 ('748); The July 1990 parent application was assigned No. 550,757 ('757).

filing date of the parent application. See Daniel Campau Affidavit. MMI did not submit any expert testimony on whether the parent application sufficiently disclosed the claims of the '371 patent at issue. Rather, MMI's motion relies solely on a textual comparison of the two applications.

Issues Regarding the October 1989 Display and
Upper Body and Lower Body Blankets.

MMI participated in a trade show at a meeting of the Society of Anesthesiologists (the 1989 ASA Meeting) at which it displayed both an upper and a lower body blanket. See AMI's Memo in Opposition at 5. In 1989 it published a brochure showing an upper body blanket in use. See Ex. E to Jimenez Declaration. AMI does not dispute that it publicly used and displayed upper and lower body blankets covered by the '371 patent in October 1989. See AMI's Memo at 5. In another case involving these parties in federal court in St. Louis, Missouri, AMI, in a motion for summary judgment, stated that in 1989 it had designed an upper body blanket with two inlets and had publicly used and displayed the blanket at the 1989 ASA Meeting. See Ex. C to Jimenez Declaration.

III. CONCLUSIONS OF LAW

A. Standard of Review

The Supreme Court has held that summary judgment is to be used as a tool to isolate and dispose of claims or defenses that are either factually unsupported or are based on undisputed facts. Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986); Hegg v. United States, 817 F.2d 1328, 1331 (8th Cir. 1987). Summary judgment is proper, however, only if examination of the evidence in a light most favorable to the non-moving party reveals no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986).

The test for whether there is a genuine issue of material fact is two-fold. First, the materiality of a fact is determined from the substantive law governing the claim. Only disputes over facts that might affect the outcome of the suit are relevant on summary judgment. Liberty Lobby, 477 U.S. at 252; Lomar Wholesale Grocery, Inc. v. Dieter's Gourmet Foods, Inc., 824 F.2d 582, 585 (8th Cir. 1987), cert. denied, 484 U.S. 1010 (1988). Second, any dispute of material fact must be "genuine." A dispute is genuine if the evidence is such that it could cause a reasonable jury to return a verdict for either party. Liberty Lobby, 477 U.S. at 252. It is

the non-moving party's burden to demonstrate that there is evidence to support each essential element of his claim. Celotex, 477 U.S. at 324.

Patent invalidity must be shown by clear and convincing evidence. Verdegall Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631 (Fed.Cir. 1987). Summary judgment may be granted only when the moving party has established a right to judgment with such clarity so as to leave no room for controversy. Woods v. Rhodes, 994 F.2d 494, 499 (8th Cir. 1993); Vacca v. Viacom Broadcasting of Mo., Inc., 875 F.2d 1337, 1339 (8th Cir. 1989).

AMI argues that summary judgment is inappropriate when the filing date of a CIP application is at issue. See AMI Memo in Opposition at 9-10. (citing see Vas-Cath, Inc., v. Mahurkar, 935 F.2d 1555, 1563 (Fed.Cir. 1991)). This assertion is wrong. While it is true that the sufficiency of the disclosure in a parent application with respect to the requirements of Section 112 must be determined on a case-by-case basis, e.g., Eiselstein v. Frank, 523 F.3d 1035, 1039-40 (Fed. Cir. 1995); Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed.Cir. 1994), and although in certain circumstances, there may be questions of fact involved in determining whether an application meets the requirements of Section 112, the ultimate conclusion is one of law and is subject

to the well-known and often quoted "genuine issue of material fact" standard. See e.g., Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

B. AMI is Not Entitled to a Filing Date of July 10, 1990 for Claims 1, 3, 4 and 8 of the '371 Patent.

A CIP application is an application which contains subject matter from a prior application and which may contain additional matter not disclosed in the prior application. See Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed.Cir. 1994). A CIP application can be entitled to different filing dates for different claims. Id. Claims containing any matter introduced in the CIP are accorded the filing date of the CIP application. Id. However, matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application. Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed.Cir. 1994). The mere fact of filing a CIP application is not determinative that the application contained new matter. Id. at 559. To qualify as a "disclosure" and thus enjoy the benefit of the prior application, the prior application must satisfy the requirements of 35 U.S.C.

§ 112. This section of the patent code provides as follows:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art...to

make and use the same...

35 U.S.C. § 112, first paragraph.

In order to determine whether the disclosure of the prior application is sufficient under §112, the fact finder must determine if one skilled in the art, reading the original specification, would immediately discern the limitation at issue in the prior application. Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed.Cir. 1994). In other words, does the "disclosure of the application relied upon reasonably convey to the artisan that the inventor had possession at that time of the later claimed subject matter?" Id. (citing Wang Labs., Inc. v. Toshiba Corp., 993 F.2d 858, 865 (Fed. Cir. 1993) (quoting Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). Whether the original description complies with the requirement of §112 must be determined on a case-by-case basis. Eiselstein v. Frank, 52 F.3d 1035, 1039 (Fed. Cir. 1995) (citing Vas-Cath, 935 F.2d at 1561). Because of the fact-specificity of these cases, it is readily apparent that each case involving the question of compliance with the description requirement of §112 must be decided on its own facts. Vas-Cath, 935 F.2d at 1562 (citing In re Driscoll, 562 F.2d 1245, 1250 (CCPA 1977)). "Thus, the precedential value of cases in this area is extremely limited." Id. (quoting In Re Driscoll, 562

F.2d at 1250).

As explained more fully below, the court concludes that the July 10, 1990 parent application does not sufficiently disclose claims 1, 3, 4, and 8 of the '371 patent to entitle these claims to the July 10, 1990 filing date. Although MMI did not submit expert testimony on the issue of whether the '757 application reasonably conveyed to a "person skilled in the art" that AMI had possession at that time of claims 1, 3, 4 and 8 of the '371 patent, the court concludes that in this case, such testimony is not required. The dispute here does not involve highly technical or scientific questions, but rather issues which are readily accessible to the court. Accordingly, the court concludes that a textual comparison of the two applications quite clearly reveals the absence of any disclosure in the July 10, 1990 parent application of the disputed claims of the '371 patent.

1. Claim 1

Claim 1 of the '371 patent is directed toward a thermal blanket for covering and bathing a portion of a patient's body from the pelvic area to the feet in a thermally controlled inflating medium. See Exhibit B to Lervick Aff. at column 8 lines 33 to column 11 lines 38. In support of its position that Claim 1 was disclosed in the July 10, 1990 application, AMI states that the parent

application "clearly indicates that the thermal blanket has a flexible base sheet with a head end, foot end and two edges...and a plurality of apertures...." AMI Memo in Opp. at 13 (citing Exhibit A to Lervick Aff. at 10 and figs. 1, 2, & 4). AMI recites additional aspects of the parent application which it contends support a finding that claim 1, a lower body blanket, was sufficiently disclosed in the parent application, including: "a blanket with an overlying flexible material sheet...attached to the flexible base sheet by a plurality of discontinuous seams"; the "formation of a plurality of communicating inflatable chambers;" "substantial longitudinal disposition over the patient's body;" and a "continuous seam near the head end..." *Id.* at 13-14. AMI argues that the presence of these elements go toward establishing that the lower body blanket covered in claim 1 of the '371 patent was disclosed in the parent application.

In addition, AMI offers the expert affidavit of Daniel N. Campau. See AMI's Exhibit A. AMI argues that Campau's opinion is that the parent application makes numerous statements indicating that the blanket can be positioned on the patient's body at various places. Campau's entire statement regarding claim 1 is as follows:

The invention of Claim 1 provides for a thermal blanket which covers a portion of a patient's body, specifically the area extending from the pelvic region to the feet.

I find that this invention is inherent in the teaching of the '757 application. There is clear recognition that care sites must be kept visible and clean ('757 application pp. 4-5). For example, the '757 application ... describes how the blanket can be drawn up to the chin area so that the absorbent bib can be placed laterally up the neck of the patient. If the care site is above the pelvic area, it is inherent to limit the extent of the blanket to the region below the care site. Shorter blankets are contemplated in the '757 application at pg. 11. Removal of the bib and tab leaves the viewing recess defined by the continuous seam at the head end, as illustrated in Figure 6. This configuration is that required in a blanket used to cover the lower body region.

Campau Aff. at 2 (emphasis added).

First, regarding the elements of the parent application which are present in the '371 patent, the court concludes that all of these elements are merely the basic components of any inflatable warming blanket, i.e., a blanket with a flexible top sheet and a bottom sheet which are attached at the seam and which contain inflatable chambers. These are components which would exist in any size warming blanket, regardless of what portion of the body to which the blanket is directed.

Second, regarding the Campau affidavit, the court concludes that the affidavit utterly fails to explain how the parent application discloses a lower body blanket. The first sentence is merely a statement of fact; the second statement is conclusory; the third sentence is a non-sequitur and is also misleading. In the

parent application, the recognition that "care-sites" must be kept visible and clean is made in direct reference to "care-sites" in the vicinity of the head and face. See Lervick Aff., Ex. A at 5. This does not teach or even suggest that a blanket which only covers the lower half of the body, i.e., the pelvic region to the feet, is an alternative means for keeping the face and neck area clean and visible. Nor is it necessarily "inherent" that if a "care-site" is above the pelvic region, that a blanket which only covers the lower half of the body is required. One obvious flaw in such a conclusion is the problem of how the remainder of the body is kept warm if the thermal blanket is only a lower body blanket.

In sum, the court concludes that claim 1 of the '371 patent is not disclosed in the July 10, 1990 parent application.

2. Claim 3

Claim 3 of the '371 patent is dependent upon claim 1; it adds the concept of including an attachment means to the head end of the blanket. See Exhibit B to Lervick Aff., column 11, lines 42-45. AMI argues that use of an attachment in combination with the blanket described in claim 1 is sufficiently disclosed in the parent application. In support of this argument, AMI relies upon Campau's opinion, which states in full:

This claim provides for attachment means at the head end for

adhering the head end to the pelvic area to prevent the migration of air from under the blanket toward a care site. This claim is contemplated by [the] '757 application. In the '757 application at pp. 3-4 it says that "The absorbent bib also acts to some extent to seal the head end of the inflated structure." This clearly contemplates the use of other means to provide the requisite seal. Adhering the head end to the blanket to the pelvic area is a logical way to practice this teaching.

Campau Aff. at 2 (emphasis added).

The court finds no logic in these statements. It appears quite clear to the court that the statement from the parent application quoted in the Campau affidavit, "acts to some extent to seal the head end of the inflated structure" does not "clearly contemplat[e] the use of other means to provide the requisite seal." The language quoted from the parent application does not suggest that a seal is required. Rather, the quotation from the application merely indicates that the bib has the desired, but merely the incidental effect of acting as a seal "to some extent." Thus it cannot be argued that use of other means to create a seal is contemplated. Moreover, even if the parent application contemplates a required seal, nothing in the application suggests an attachment as an alternative means.

In sum, the court concludes that the July 10, 1990 application does not disclose claim 3 of the '371 patent.

Claim 4

Similar to claim 1, claim 4 relates to an inflatable thermal blanket which covers and bathes a portion of a patient's body. See Exhibit B to Lervick Aff., column 11, lines 58-60. In claim 4, the blanket is positioned across the arms and chest of a patient's body. Id. AMI argues that the elements of claim 4 are disclosed in the following portions of the parent application: "a flexible base sheet which has a plurality of apertures;" "the overlying flexible material sheet is attached to the base sheet by a plurality of discontinuous seams;" and "the production of communicating inflatable chambers is also disclosed." AMI's Memo in Opposition at 16. AMI also argues that the parent application reveals that the blanket "could be repositioned at numerous locations over the patient's body in anticipation of the teaching of claim 4" that the "inflatable chambers are transversely disposed over the portion of the patient's body extending across the arms and chest." See AMI Memo in Opp. at 16. In support of this argument, AMI's relies on the opinion of its expert who states in full:

...It is clear that the inventors were aware that a blanket could be positioned in many ways. They were aware that various patterns of communicating chambers could be used ('757 application, p.10). They were aware that the blanket could be drawn up to the patient's chin

if needed to provide absorbency laterally up the neck of the patient. ('757 application, p.10). Any special problem created by transverse disposition is resolved by the teaching of the '757 application. If, for example, there is also a need to extend the patient's arms and provide a thermal blanket that encloses them, it is inherent in the teaching of the '757 application to provide a blanket that extends over this area. Disposing the blanket transversely is one inherent embodiment of the teaching of '757 application.

Campau Aff. at 3 (emphasis added).

Contrary to the assertion of AMI's expert, the court concludes that there is simply no suggestion in the parent application as to why the pattern of inflatable tubes might be replaced by other suitable patterns of communicating, inflatable chambers. See Lervick Aff., Ex. A at 10. Similarly, neither AMI or Campau provide any explanation for how Campau leaps from the statement in the parent application that the blanket could be drawn up to the patient's chin if needed to provide lateral absorbency to the conclusion that this discloses claim 4, a blanket that covers the arms and chest. The remainder of Campau's statements regarding claim 4 and the parent application are conclusory. In sum, the court concludes that the parent application does not disclose claim 4 of the '371 patent.

4. Claim 8

Claim 8 is directed toward an embodiment of the invention

which is placed across the arms and chest of the patient's body. AMI recites the following elements of the parent application which it contends are incorporated into claim 8: an inflatable covering with inflatable chambers which are substantially transversely disposed over a portion of the patient's body and extending across the arms and chest of the patient; an inflating inlet; the undersurface of the inflatable cover has an array of apertures; and the existence and use of a recess for accommodating the curvature of a patient's torso. Again, AMI relies on its expert, who states:

...The first recess is similar to the head end recess taught in the '757 application. The claim recites the specific function of closing off the inflatable chambers adjacent a peripheral margin. This function follows directly from the combination of the recess and the transverse blanket orientation....

The second recess is for accommodating the patient's torso. It also closes off the inflatable chambers adjacent a second peripheral margin. The need for the second recess across the patient's torso follows from the teaching of the '757 application...which calls for a "non-inflated blanket recess...which remains smooth and flat when the blanket is inflated and erected." It follows that this recess which accommodates the patient's torso allows the covering to be adhered to the patient's chest to prevent the migration of air from underneath the blanket. The fact that this recess also closes the inflatable chambers adjacent a peripheral edge is an inherent feature of the structure.

Campau Aff. at 3 (emphasis added).

First, regarding the elements of the parent application which

AMI identifies as present in claim 8, the court observes that these are components which would exist in any size warming blanket, regardless of what portion of the body to which the blanket is directed. Second, the court observes that claim 8, like claim 4, is directed toward a blanket covering the arms and chest of a patient. Above, the court concluded that there is no basis for concluding that claim 4 is disclosed in the parent application.

Claim 8 also contains two recesses. Although the parent application contains one recess which allows viewing of the head, there is no language in the parent application which suggests a second recess, much less a second recess "for accommodating the curvature of the patient's torso" as found in claim 8. Additionally, there is nothing in the '757 application corresponding to, or suggesting an attachment at the second recess for adhering the blanket to the patient as required by claim 8. The court finds Campau's statement regarding the first recess contained in claim 6 and the disclosure of a head end recess in the parent application conclusory. Campau's statements regarding the second recess are illogical: the "non-inflated blanket recess" in the parent application occurs at the chin area and cannot be imagined to "accommodate the patient's torso" as Campau concludes. Finally, Campau fails to explain how the attachment required in claim 8 is

anticipated in the parent application.

In sum, the court concludes that claim 8 of the '371 patent is not disclosed in the parent application.

C. Claims 1, 3, 4, and 8 of the '371 Patent are Invalid because AMI Sold and Displayed these Claims More than One Year prior to the Effective Filing date of the Claims.

To prove invalidity under 35 U.S.C. Section 102(b), a person challenging a patent must show that one or more stated requirements are not met. This section of the patent code states:

A person shall be entitled to a patent unless:

(b) the invention was...described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for a patent in the United States,....

35 U.S.C. §102(b).

AMI does not dispute that in October 1989, it publicly used and described the upper body and lower body blankets covered by the disputed claims. AMI's Memo in Opposition at 5. Above the court concludes that claims 1, 3, 4, and 8 of '371 patent are not entitled to the July 1990 filing date of the alleged parent application, the '757 application. As the '748 application was filed in January 1991, over a year after claims 1, 3, 4, and 8 of the application were publicly used and described, the court concludes that AMI was not entitled to a patent for these claims and those claims are

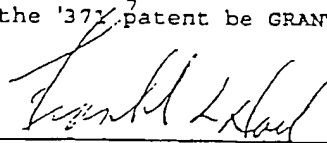
consequently invalid. 35 U.S.C. §112(b).

IV. RECOMMENDATION

Based upon the foregoing, and all the records, files and proceedings herein, IT IS HEREBY RECOMMENDED that:

1. Defendant's motion for summary judgment of invalidity of claims 1, 3, 4, and 8 of the '372 patent be GRANTED.

Dated: November 18, 1996


Franklin L. Noel
Chief U.S. Magistrate Judge

Under D.Minn.L.R. 72.1(c)(2) any party may object to this Report and Recommendation by filing with the Clerk of the Court, and serving all parties by 12-6-96, a writing which specifically identifies those portions of this Report to which objections are made and the basis of those objections. Failure to comply with this procedure shall operate as a forfeiture of the objecting party's right to seek review in the Court of Appeals. A party may respond to the objecting party's brief within ten days after service thereof. All briefs filed under this rule shall be limited to ten pages. A judge shall make a de novo determination of those portions to which objection is made.

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Fourth Division

AUGUSTINE MEDICAL, INC., :
 :
Plaintiff, :
 :
v. : Civil Action No. 4-94-CV-875
 :
MALLINCKRODT GROUP INC. and :
MALLINCKRODT MEDICAL, INC., :
 :
Defendants. :

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR PARTIAL
SUMMARY JUDGMENT OF INVALIDITY OF CLAIMS 1, 3,
4 AND 8 OF PLAINTIFF'S U.S. PATENT NO. 5,405,371

INTRODUCTION

Defendants, Mallinckrodt Group Inc. and Mallinckrodt Medical, Inc. (collectively "MMI"), move for partial summary judgment of invalidity of claims 1, 3, 4 and 8 of Plaintiff Augustine Medical, Inc.'s ("AMI's") U.S. Patent No. 5,405,371 (the "'371 Patent"). The grounds for the motion are that there are no genuine issues of material fact in dispute as to the invalidity of these claims by virtue of AMI's admitted public use of and placing on sale a product covered by the claims more than one year prior to the effective filing date of the claims. MMI is, therefore, entitled to judgment of invalidity of such claims as a matter of law.

The general subject matter of the '371 Patent, an improved "self-erecting" type inflatable blanket, was previously discussed in detail in MMI's Partial Motion for Summary Judgment of Non-Infringement, filed June 23, 1995 ("MMI's Motion for Summary Judgment of Non-Infringement"). After consideration of the parties' positions, the Court issued a Report and Recommendation

dated March 18, 1996 (the "Report"). (Both sides submitted objections to portions of the Report and such objections are sub judice.) In the Report, the Court interpreted the "self-erecting" feature required by the claims of the AMI patents-in-suit, including the '371 Patent.

Subsequent to issuance of the Report, MMI learned that the claims of the '371 Patent were invalid because AMI had, in October of 1989, more than one year prior to the effective filing date of those claims (January 8, 1991), publicly used and placed on sale (and described in a printed publication) thermal blanket products covered by the claims. MMI first became aware of this evidence of AMI's public use and sale by virtue of AMI's submission of evidence to the U.S. District Court for the Eastern District of Missouri in connection with AMI's Motion for Summary Judgment filed January 8, 1996 ("AMI's St. Louis Motion"), in Civil Action No. 4:95CV00514 MLM.¹

As is described below, AMI's own unequivocal admissions in its St. Louis Motion and at depositions taken in connection with that Motion establish that claims 1, 3, 4 and 8 of the '371 Patent are invalid under 35 U.S.C. § 102(b) because the subject matter of those claims was described in a printed publication and was

¹ This case is currently pending in the United States District Court in St. Louis, Missouri, between MMI and AMI (the "St. Louis Action").

publicly used and placed on sale more than one year prior to the effective filing date of the '371 Patent.²

MATERIAL FACTS NOT IN DISPUTE

The Claimed Subject Matter

1. The '371 Patent (copy attached to the accompanying Declaration of Celine M. Jimenez ("Jimenez Decl.") at Exh. A) has a total of nine claims generally directed to improvements to the "self-erecting" AMI type inflatable thermal blanket. See Jimenez Decl. Exh. A, column 1, lines 43-44 ("We have improved the clinical usefulness of our self-erecting airflow cover"). AMI has asserted five claims of the '371 Patent, claims 1-4 and 8, against two of MMI's warming blanket products.

2. Claims 1-3 of the '371 Patent, directed to a lower body style blanket for use in the operating room to cover a patient's pelvis and legs during surgery, are asserted against MMI's lower body blanket Model No. 503-0830 (the "'830 blanket"). Claims 4 and 8 of the '371 Patent, directed to an upper body style blanket for use in the operating room to cover a patient's chest and arms (outstretched) during surgery, are asserted against MMI's upper body blanket Model No. 503-0820 (the "'820 blanket").

² AMI's failure to disclose to the Patent Office its prior publication, public use and placing on sale of blankets covered by claims of the '371 Patent during the prosecution of the Patent renders all claims of the Patent invalid for fraud and inequitable conduct. See 37 C.F.R. § 1.56. However, because the issue of inequitable conduct involves questions of intent and motivation which are factual in nature, in order to avoid the possibility that AMI would attempt to raise factual disputes (although invalidity for inequitable conduct should not really be subject to serious challenge), inequitable conduct is not the subject of this Motion.

The Lower Body Blanket Claims

3. Claim 1 of the '371 Patent recites:

In a self-erecting inflatable thermal blanket for covering and bathing a portion of a patient's body in a thermally-controlled inflating medium, the improvement comprising:

- a) a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;
- b) an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;
- c) said inflatable chambers in said covering for substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body;
- d) a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chamber; and
- e) a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet.

Id. at column 11, lines 14-38.

4. Claim 3, which is dependent on claim 1, further recites "an attachment means at said head end for adhering said head end to said pelvic area" Id. at column 11, lines 42-45.'

5. The lower body blanket of claims 1 and 3 is described and shown in the '371 Patent in Figs. 8 and 9 (Figs. 8 and 9 are

' In order to avoid the possibility that AMI would attempt to raise factual disputes as to obviousness (although there should be no genuine issue of material fact in dispute), claim 2 of the '371 Patent, which recites a non-inflatable extension for covering the feet, is not the subject of this Motion. MMI does intend to show at trial that claim 2 of the '371 Patent is invalid under 35 U.S.C. § 103 for obviousness in view of prior art showing that it is conventional to cover the feet in the inflatable blanket art.

reproduced below). See also Id. at column 3, line 32 - column 9, line 44.

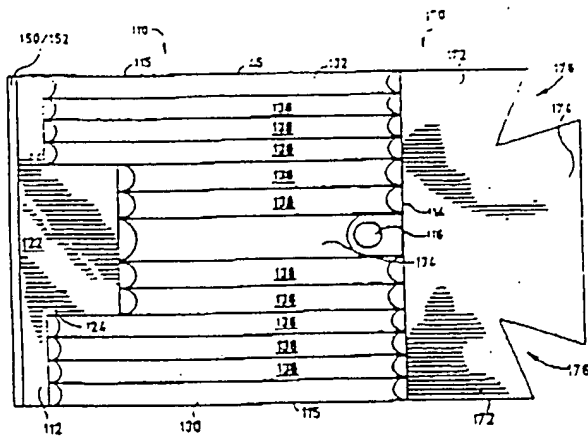


FIG. 8

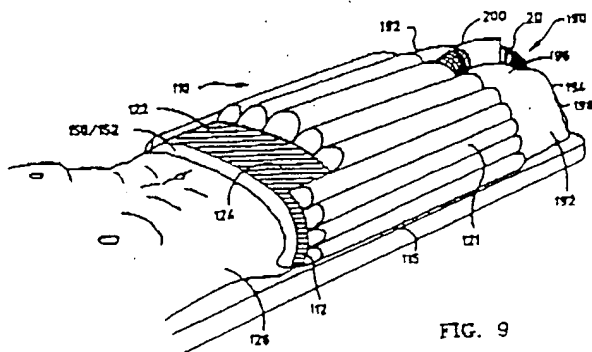


FIG. 9

6. The lower body blanket of claims 1 and 3 covers the pelvic area and legs of the patient. Id. at column 8, lines 35-39. The blanket has a head end 112, a foot end 114, a pair a lateral edges

115, and a plurality of apertures in the base sheet through which air is exhausted into the interior of the erected structure formed by the inflated blanket. Id. at Fig 8; column 8, lines 43-54. The overlying sheet is attached to the base sheet so as to form a parallel array of elongated tubes 130, 132, 134 and 138. Id. at Figs. 8 and 9; column 9, lines 12-16. Figs. 8 and 9 show a non-inflatable section 122 extending between a continuous seam (continuous seam 40 shown generally at Fig. 2 and in column 5, lines 14-22) and the head end of the blanket. The non-inflatable section includes an end portion of the flexible sheet of the blanket 150/152. Figs. 8 and 9 show an adhesive strip 124 for adhering the head end of the blanket to the patient's pelvic area. Id. at column 8, line 58 - column 9, line 7.

The Upper Body Blanket Claims

7. Claim 4 of the '371 Patent recites:

In a self-erecting, inflatable thermal blanket for covering and bathing a portion of a patient's body in a thermally-controlled inflating medium, the improvement comprising:

- a) a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;
- b) an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;
- c) said inflatable chambers for substantially transverse disposition over a portion of said patient's body and extending substantially across the arms and chest of said patient's body;

- d) a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers; and
- e) a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet.

Id. at column 11, lines 46-68.

8. Claim 8 of the '371 Patent recites:

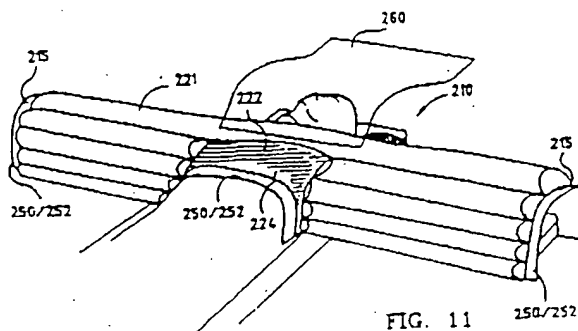
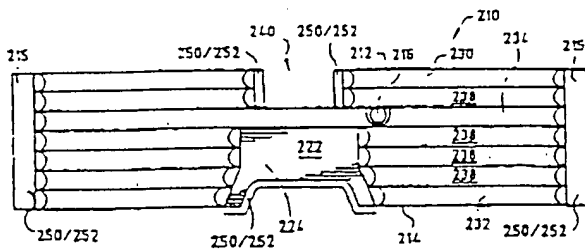
An inflatable thermal blanket for convectively controlling the temperature of a portion of a patient's body, comprising:

- a) a self-erecting inflatable cover with an undersurface and a plurality of substantially elongate, inflatable chambers for substantially transverse disposition over a portion of a patient's body and extending substantially across the arms and chest of said patient's body;
- b) an inflating inlet for admitting a thermally-controlled inflating medium into said chambers for erection of said inflatable covering;
- c) an array of apertures in said undersurface for exhausting a thermally-controlled inflating medium from said chambers through said undersurface and said patient's body;
- d) a first recess in said inflatable chambers extending across and closing off first inflatable chambers adjacent a first peripheral margin of said inflatable covering;
- e) a second recess in said inflatable chambers extending across and closing off second inflatable chambers adjacent a second peripheral margin of said inflatable covering opposite said first peripheral margin;
- f) the second recess for accommodating the curvature of said patient's torso; and
- g) attachment means at said second recess for adhering said inflatable covering to said chest and preventing migration of air from underneath said thermal blanket toward a care site.

Id. at column 12, lines 11-39.

9. The upper body blanket of claims 4 and 8 is described and shown in the '371 Patent at Figs. 10 and 11 (Figs. 10 and 11 are reproduced below). See also *Id.* at column 9, line 45, *et seq.*

FIG. 10



10. The upper body blanket of claims 4 and 8 is a self-erecting inflatable cover with a head end 212, a foot end 214, a pair of lateral edges 215 and inflation inlet cuff 216. *Id.* at Fig. 10; column 9, lines 48-55. The overlying sheet is attached to the base sheet of the blanket so as to form an array of elongated tubes 230, 232, 234 and 238, disposed transversely over the arms and chest of the patient. *Id.* at column 10, lines 18-22 and 34-37; Figs. 10 and

11. A non-inflatable section extending between a continuous seam and the head end of the blanket and including an end portion of the flexible blanket sheet is also shown. See generally Id. at column 9, lines 48-50 (and by reference Fig. 1 and column 5, lines 14-22).

11. First recess 240 at the head end of the blanket and second recess at the torso end of the blanket are also shown and Figs. 10 and 11. Id. at column 9, line 66 - column 10, line 2; column 10, lines 22-30. Adhesive strip 224 for attaching the blanket to the patient's chest is shown in Fig. 10. Id. at column 10, lines 3-17.

The Effective Filing Date Of The Claims At Issue

12. The '371 Patent issued from a patent application, Serial No. 638,748, which was filed by AMI on January 8, 1991 (hereinafter the "'371 Application"). This application was what is known under the Rules of Patent Practice as a "continuation-in-part" of an earlier application, Serial No. 550,757 filed July 10, 1990 (hereinafter the "Parent Application"). Id. at p. 1, "Related U.S. Application Data" at part [63]; and see copy of Request for Filing Continuation-in-Part Application at Jimenez Decl., Exh. B.

13. A "continuation-in-part" is an application which contains subject matter, some of which was contained in an earlier "parent" application and some of which is new. The subject matter of the continuation-in-part application which was contained in the earlier parent application is entitled to the filing date of the parent application. The new material in the continuation-in-part application which was not contained in the parent application is

entitled to the filing date of the continuation-in-part application. See 35 U.S.C. § 120.

14. Figs. 1-7 of the '371 Patent, which show generally an AMI-type self-erecting blanket, were contained in the Parent Application; however, Figs. 8-11 of the '371 Patent which specifically show the upper and lower body operating room blankets covered by the claims at issue and the accompanying description to the Figures were new subject matter in the '371 Application and were not contained in the Parent Application. The subject matter of Figs. 8-11 and the accompanying description of them in the specification of the '371 Patent comprise, therefore, what is known as the "new matter" in the '371 Application.' Id., Exh. B. This new matter is not entitled to the filing date of the Parent Application, but rather, is entitled to the date this subject matter was filed, January 8, 1991.

15. The claims at issue which are described and enabled by Figures 8-11 and their accompanying description are, therefore, entitled to the filing date of the '371 Application, namely, January 8, 1991. See 35 U.S.C. § 120.

AMI's Motion For Summary Judgment In The St. Louis Action

16. On January 8, 1996, AMI filed a Motion for Summary Judgment in the St. Louis Action ("AMI's St. Louis Motion") and urged that the two MMI patents asserted against AMI in the St. Louis Action,

* The description added to the specification of the '371 Patent which was not contained in the Parent Application is found in the '371 Patent at column 1, line 59 through column 2, line 2; column 2, lines 21-28 and 48-51; column 3, lines 18-21 and column 8, line 32 through column 11, line 3. Id., Exh. A.

U.S. Patent Nos. 5,360,439 and 5,384,924 (collectively the "MMI Patents") were invalid. Copies of excerpts of AMI's Memorandum in support of its St. Louis Motion are attached to the Jimenez Decl. at Exh. C. Copies of the MMI Patents are attached to the Jimenez Decl. at Composite Exh. D.

17. In its St. Louis Motion, AMI stated that in 1989 it had designed an upper body blanket with two inlets, had described that blanket in a printed brochure distributed in October of 1989 (the "1989 Brochure"),⁵ had publicly used and displayed the blanket at an October 1989 trade show (the "1989 Trade Show"), and had placed the blanket on sale at that trade show.⁶ (These activities will be collectively referred to as "AMI's 1989 Activities").⁷ AMI urged in its St. Louis Motion that in view of its 1989 Activities, MMI's Patents, which cover upper body blankets with more than one air inlet, were invalid under 35 U.S.C. § 102 because AMI's 1989 Activities occurred more than one year prior to the filing date of the MMI Patents.⁸ See Exh. C at 9-12.

⁵ Copy of 1989 Brochure submitted with AMI's St. Louis Motion is attached as Exh. E to the Jimenez Decl.

⁶ Copies of photographs submitted with AMI's St. Louis Motion which AMI asserted showed its 1989 public use and placing on sale of upper and lower body blankets are attached as Composite Exh. F to the Jimenez Decl.

⁷ AMI's St. Louis Motion did not directly concern AMI's lower body blankets; however, in the course of taking discovery in connection with the St. Louis Motion, MMI learned in more detail that AMI had also displayed, used and placed on sale a lower body blanket at the 1989 Trade Show.

⁸ The MMI Patents each have effective filing dates of August 3, 1992. Jimenez Decl., Exh. D.

18. Specifically, AMI stated in its St. Louis Motion, after describing how AMI "widely distributed" the 1989 Brochure at the 1989 Trade Show, "[c]learly, the distribution of the [1989] Dual Port Brochure at the 1989 ASA Meeting meets the printed publication requirements of 35 U.S.C. § 102(b)." Id. at 11.

19. AMI also stated in its St. Louis Motion that its blankets displayed and used at the 1989 Trade Show were placed "on sale" for the purposes of § 102(b). Specifically AMI stated:

The Dual Port [1989] Brochure was distributed at the 1989 ASA Meeting to encourage sales of the product. The "live" display of the Dual Port Warming Cover served the same purpose to provoke customer interest and generate sales. This commercial activity clearly qualifies as offers for sale . . . under 35 U.S.C. § 102(b).

Id. at 12.

20. In sum, in an attempt to invalidate MMI's Patents, AMI asserted and admitted that its 1989 Activities constituted a description in a printed publication for the purposes of § 102(b), and constituted a public use and placing of the blankets on sale for purposes of 35 U.S.C. § 102(b). Id. at 11 - 12.

21. MMI opposed AMI's St. Louis Motion on the grounds, inter alia, that the AMI blankets shown at the 1989 Trade Show did not contain a critical element of the claims of MMI's Patents, namely, the "means to selectively open said multiple inlet ports comprising a tear strip."

' Claim 1 of the MMI Patents, in addition to reciting multiple air inlets, recites "means to selectively open" the inlets wherein the means comprises "a tear strip." Id., Exh. D.

22. MMI conducted discovery in connection with AMI's St. Louis Motion, and specifically in connection with the AMI blankets that were publicly shown, used and placed on sale at the 1989 Trade Show (and described in the 1989 Brochure). Specifically, MMI took oral depositions of the designers of those AMI blankets, Scott Augustine and Randy Arnold, both of whom attended the 1989 Trade Show. Copies of excerpts of the deposition transcripts of Scott Augustine and Randy Arnold are attached to the Jimenez Decl. at Exhs. G and H, respectively.

23. During their depositions, Scott Augustine and Randy Arnold confirmed under oath that AMI upper and lower body blankets were publicly used and placed on sale at the October 1989 Trade Show (and were described in the 1989 Brochure distributed at the Trade Show). Significantly, they also unequivocally confirmed that these blankets had all of the features required by claims 1, 3, 4 and 8 of the '371 Patent. Id., Exhs. G-I.

24. In sum, (apparently unaware that they were doing so), AMI's Scott Augustine and Randy Arnold effectively and unequivocally confirmed under oath that the '371 Patent was invalid. Id.

25. Specifically, and as is described in detail at Jimenez Decl., Exh. I, the AMI lower body blanket shown at the 1989 Trade Show and described in the 1989 Brochure was self-erecting with a head end, foot end, two edges and a plurality of apertures (Id., Exh. E pp. 1-3 and p. 4, col. 3, Exh. F and Exh. G at p. 121, line 19 - p. 122, line 7); had a plurality of discontinuous seams which formed a plurality of communicating inflatable chambers (Id.); had

inflatable chambers in a substantially longitudinal disposition over the area of the patient from the pelvis to the feet (Id., Exh. E, p. 3, Exh. F, and Exh. G at p. 121, lines 19-21); had a non-inflatable section extending substantially between a continuous seam and the head end of the blanket and including an end portion of the blanket sheet (Id., Exh. G at p. 120, lines 6-11 and p. 121, lines 9-14, and Exh. H at p. 103, lines 2-6, p. 108, lines 4-7); and had means for adhering the blanket at the head end to the pelvic area of the patient (Id., Exh. G at p. 120, line 12 - p. 121, line 4 and Exh. H at p. 104, lines 5-20).

26. The AMI upper body blanket shown at the 1989 Trade Show and described in the 1989 Brochure was self-erecting (Id., Exh. E at p. 3, Exh. F, and Exh. G at p. 115, lines 22-24 and p. 116, lines 4-7); was made of a flexible base sheet having a head end, a foot end, two edges and a plurality of apertures, with the overlying sheet attached to the base sheet by a plurality of discontinuous seams which form a plurality of communicating inflatable chambers (Id., Exh. E at pp. 1-3 and 4, col. 3, and Exh. G at p. 115, lines 18-21 and p. 116, lines 8-18); had inflatable chambers for substantially transverse disposition over the patient's body extending across the arms and chest (Id., Exh. E at pp. 2 and 3, Exh. F, Exh. G at p. 116, lines 8-18 and Exh. H at p. 91, lines 4-8); had a continuous seam near the head end which closes off the end of the inflatable chambers (Id., Exh. G at p. 111, lines 19-21 and p. 113, lines 15-18); and had a non-inflatable section of the blanket extending substantially between the continuous seam and the

head end of the blanket (Id., Exh. G at p. 112, line 6 - p. 113, line 18 and Exh. H at p. 97, line 4 - p. 98, line 11).

27. The AMI upper body blanket shown at the 1989 Trade Show and described in the 1989 Brochure also had an inflating inlet (Id. Exh. E); a first recess (or cut-out) at the head end of the blanket (Id., Exh. G at p. 110, lines 17-20, p. 113, lines 15-18, and Exh. 1 attached thereto); a second recess extending across and closing off a second peripheral margin opposite the first recess to accommodate the patient's torso (Id. at p. 114, lines 3-6 and p. 114, line 18 - p. 115, line 17, and Exh. H at p. 92, lines 2-4, 11-14 and p. 95, lines 4-5); and tape for attaching the blanket to the patient's chest (Id., Exh. G at p. 110, lines 17-20 and p. 114, lines 3-17, and Exh. H at p. 94, lines 6-11).

28. A detailed claim chart matching the claim language at issue with the features that Scott Augustine and Randy Arnold testified were present in the AMI upper and lower body blankets on sale at the 1989 Trade Show and described in the 1989 Brochure is attached to the Jimenez Decl. at Exh. I.

DISCUSSION

Applicable Law

In order for subject matter to be patentable, it must be new (novel) and non-obvious. Novelty is discussed in the Patent Statute at 35 U.S.C. § 102. Section 102 of the Patent Statute states:

A person shall be entitled to a patent unless -

- (b) The invention was patented or described in a printed publication in this or a foreign country or in public use

or on sale in this country, more than one year prior to the date of the application for patent in the United States .

Under 35 U.S.C. § 102(b), a patentee is barred from obtaining a patent if the subject matter of the patent was described in a printed publication or was in public use or on sale in this country more than one year prior to the filing date of the U.S. application for a patent. The portion of 35 U.S.C. § 102(b) which bars a patent if the product is "on sale" more than a year prior to the application filing date is commonly known as the "on sale bar." Events before the date one year prior to the filing of the patent can trigger the on sale bar. See McCarthy, J. Thomas, McCarthy Desk Encyclopedia of Intellectual Property, The Bureau of National Affairs, Inc. (1991) at 26.

The policy behind 35 U.S.C. § 102(b) is to give an inventor one year following the start of public disclosure or commercialization of the invention to decide whether to file an application for a patent. If no patent application is filed within that one year time frame, the right to a patent is lost. This forces the inventor to choose between seeking patent protection promptly following public disclosure (or sales activity) or taking his chances with his competitors without the benefit of patent protection. See e.g., General Electric Co. v. United States, 654 F.2d 55 (Ct. Cl. 1981).

Invalidity of a patent under 35 U.S.C. § 102 must be shown by clear and convincing evidence. See Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987). A claim is invalid

under Section 102 if each element of the claim is found or described, expressly or equivalently, in a single prior art disclosure. Id. Whether an invention was described in a printed publication or in public use or on sale within the meaning of 35 U.S.C. § 102(b) is a question of law. See Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc., 984 F.2d 1182, 1186 (Fed. Cir. 1993). Summary judgment on the issue of whether a patent is invalid by virtue of the subject matter of the patent being described in a printed publication or publicly used or "on sale" more than one year prior to the filing date of the patent is proper where there are no genuine issues of material fact in dispute. Id. at 1184-85 (citing Fed. R. Civ. P. 56(c)).

Claims 1, 3, 4 And 8 Of The '371 Patent Are Invalid By
Virtue Of Their Subject Matter Being Described In A "Printed
Publication," And Being Publicly Used And Placed On Sale

In October of 1989, more than one year prior to the effective filing date of the application which resulted in the '371 Patent, namely, January 8, 1991, AMI described in printed brochures, and publicly used and placed on sale, upper and lower body blankets embodying the very subject matter of the claims at issue. Accordingly, those claims are invalid under 35 U.S.C. § 102(b).

In the present case, as described above, the evidence submitted by AMI in connection with its St. Louis Motion and its own admissions at deposition clearly and convincingly show that the blankets displayed, used and on sale at the 1989 Trade Show and described in the 1989 Brochure included each and every element of claims 1, 3, 4 and 8 of the '371 Patent. In view of these

undisputed facts, no reasonable jury could fail to find that the claims at issue here are invalid by virtue of AMI's having publicly described, used and placed on sale products covered by those claims more than one year prior to the effective filing date of the claims.

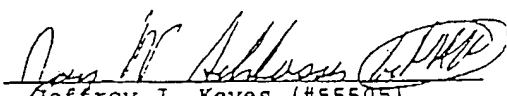
CONCLUSION

In view of the foregoing, it is clear that MMI is entitled to judgment as a matter of law that claims 1, 3, 4 and 8 of the '371 Patent are invalid under 35 U.S.C. § 102(b).

Dated: June 28, 1996

BRIGGS AND MORGAN

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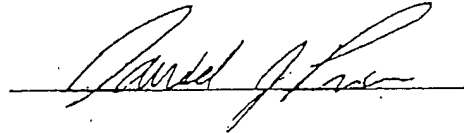
STATE OF MINNESOTA
COUNTY OF HENNEPIN

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NOTICE OF SERVICE

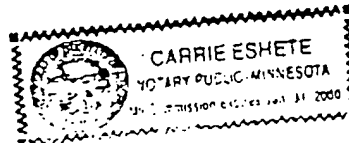
METRO LEGAL SERVICES, INC.

Daniel J. Pribek, being duly sworn, on oath says: that on the 17th day of July, 1996, at 5:05 p.m. (s)he served the attached Memorandum of Augustine Medical, Inc. in Opposition to Motion for Partial Summary Judgment, Affidavit of Daniel N. Campau, and Affidavit of Jay Lervick upon Jay W. Schlosser, Esq. therein named, personally at 2400 IDS Tower, Minneapolis, County of Hennepin, State of Minnesota, by handing to and leaving with Sam Lovejoy, receptionist, an expressly authorized agent for service for said Jay W. Schlosser, Esq., a true and correct copy thereof.



Subscribed and Sworn to before me
this 17th day of July, 1996.


Notary Public



Charge \$

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION

Civ. No. 4-94-CV-875

Augustine Medical, Inc.,

Plaintiff,

vs.

Mallinckrodt Group, Inc. and
Mallinckrodt Medical, Inc.,

Defendants.

MEMORANDUM
OF AUGUSTINE MEDICAL, INC.
IN OPPOSITION TO MOTION FOR
PARTIAL SUMMARY JUDGMENT

INTRODUCTION

Defendants Mallinckrodt Group and Mallinckrodt Medical, Inc. (collectively "Mallinckrodt") rely on unsupported legal conclusions, wrongly identified as "undisputed facts," as grounds for partial summary judgment. Specifically, Mallinckrodt asks the Court to assume that the patent claims at issue have an effective filing date of January 8, 1991. Mallinckrodt is incorrect because the subject matter of the claims at issue¹ was described in a parent application which has a filing date of July 10, 1990, six months earlier than the filing date asserted by Mallinckrodt. At the very least, whether the claims were described in the parent application is a disputed issue of fact which precludes the entry of partial summary judgment. Indeed, whether

¹ Mallinckrodt seeks summary judgment only as to claims 1, 3, 4 and 8 of AMI's patent no. 5,405,371. AMI has also asserted claim 2 of the '371 Patent against Mallinckrodt, which is not a subject of Mallinckrodt's Motion (see Mallinckrodt's Memorandum of Law at 4 n. 3) as well as United States patents '188, '320 and '102 which also are not the subject of Mallinckrodt's Motion.

subject matter is described in a parent application is an inherently factual question that is not suitable for resolution by summary judgment.

The disputed claims are entitled to a filing date of no later than July 10, 1990. As a result, the activities of Augustine Medical, Inc. ("AMI") in October 1989 upon which Mallinckrodt bases its argument cannot be cited as prior art. The one year statutory bar statute cited by Mallinckrodt in its motion -- 35 U.S.C. § 102(b) -- simply does not apply. Mallinckrodt's Motion for Summary Judgment should be denied.

FACTS

A. The '371 Patent.

United States patent no. 4,504,371 (the "'371 Patent") issued on April 11, 1995 from U.S. patent application no. 638,748 (the "'748 application"). The '748 application was a continuation-in-part application ("CIP application") which included information from three earlier filed related applications, all of which were abandoned in favor of continuations. All of the related applications are listed on the first page of the '371 Patent. See Ex. A to the Declaration of Celine M. Jimenez ("Jimenez Decl."). The specific details of each application are outlined below.

First, on October 5, 1987, AMI Medical, Inc. filed U.S. patent application no. 104,682 titled "THERMAL BLANKET" (the "great-grandparent application"). This application was abandoned on December 5, 1988.

Next, on October 2, 1988, AMI filed U.S. patent application no. 227,189 titled "THERMAL BLANKET" (the "grandparent application"). This grandparent application was a CIP of the great-grandparent application and included much of the material that is contained in the '371 Patent. The grandparent application was abandoned on July 1, 1991.

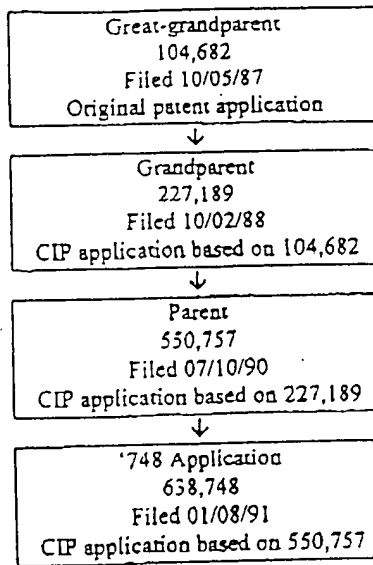
On July 10, 1990, a third CIP application was filed as U.S. patent application no. 550,757 (the "parent application"). Again, this application was titled "THERMAL BLANKET" and again contained much of the same description which exists in the '371 Patent. A copy of the parent application is attached as Exhibit A to the Affidavit of Craig J. Lervick ("Lervick Affidavit").¹

Finally, on January 8, 1991, the '748 application was filed as a CIP of the parent application. The '748 application ultimately issued as the '371 Patent.² In graphical format, the progression of related applications leading up to the '371 Patent looks like:

² The parent application was continued as U.S. application no. 887,233 on May 19, 1992 (which issued as U.S. patent no. 5,300,102).

¹ For convenient reference, the application numbers are set out below in chart form.

Application	Application Serial No.	Filing Date	Description
Great-grandparent	104,682	10/05/87	Original patent application
Grandparent	227,189	10/02/88	CIP application based on 104,682
Parent	550,757	07/10/90	CIP application based on 227,189
'748 Application	638,748	01/08/91	CIP application based on 550,757



Each application related to the '571 Patent was filed as a CIP⁴ application and claimed the benefit of its predecessor applications under the patent laws. See 35 U.S.C. § 120. Additionally, application was filed by the same inventors and was filed during the pendency of its predecessor application.

⁴ A CIP application repeats a portion of a prior application and may also add clarification, elaboration or new matter not disclosed in the earlier one. As Mallinckrodt concedes, the subject matter of the CIP application which was included in the prior application is entitled to a filing date of the prior application while new subject matter, if any, provided only in the CIP application is given the filing date of the CIP application. See Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994); see also Mallinckrodt's Memorandum of Law ¶ 13 at 9.

B. AMI's 1989 activities.

As stated in Mallinckrodt's Memorandum, in 1989 AMI published a brochure showing an upper body and a lower body blanket in use. Additionally, AMI participated in the 1989 Annual Meeting of the American Society of Anesthesiologists (1989 ASA meeting) in New Orleans, Louisiana on October 14-18, 1989. AMI displayed both an upper body and a lower body blanket at its booth (these activities collectively "AMI's 1989 activities").

AMI does not dispute that it publicly used and described upper body and lower body blankets covered by the disputed claims in October 1989. These activities are irrelevant, however, to the validity of the claims at issue. The activities did not occur more than one year prior to the July 10, 1990 filing of the parent application for the '371 Patent⁵.

ARGUMENT

I. STANDARD - SUMMARY JUDGMENT.

Summary judgment is appropriate only when the moving party demonstrates that there is no genuine issue as to any material fact and that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "Summary judgment will not lie if the dispute about a material fact is genuine, that is, if the evidence is such that a reasonable jury could return a verdict for the moving party." Anderson v. Liberty Lobby, 477 U.S. 242, 248, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202, 208 (1986).

⁵ Mallinckrodt incorrectly and misleadingly focuses its argument exclusively on the fact that AMI's disclosure of the invention in October 1989 is undisputed. See Mallinckrodt's Memorandum of Law at 16-18. Mallinckrodt fails to prove an absence of genuine dispute as to whether the subject matter of the claims was described in the July 10, 1990 parent application, a dispute which precludes summary judgment. In fact, Mallinckrodt does not address this issue at all, thus failing to meet its burden to show an absence of genuine disputes of material fact.

The role of the court is not to weigh the evidence, but instead to determine whether a genuine factual dispute exists. *Id.* at 249, AgriStor Leasing v. Farrow, 826 F.2d 732, 734 (8th Cir. 1987); Tower Ins. Co., Inc. v. Judge, 840 F. Supp. 679, 684 (D. Minn. 1993). In making this determination, "the evidence must be viewed in a light most favorable to the party opposing summary judgment". Paragon Podiatry Laboratory v. KLM Laboratories, 984 F.2d 1182, 1185 (Fed. Cir. 1993) (citing, United States v. Diebold, Inc., 369 U.S. 654, 655, 82 S.Ct. 993, 993, 8 L.Ed.2d 176 (1962)); *see also* AgriStor, 826 F.2d at 734; Tower Ins., 840 F. Supp. at 684; Minnesota Pet-Breeders, Inc. v. Schell & Kamperer, Inc., 843 F.Supp. 506, 510 (D. Minn. 1992).

As Mallinckrodt concedes, patent invalidity must be shown by clear and convincing evidence. Mallinckrodt's Memorandum of Law at 16, citing Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987). Summary judgment may be granted only when the moving party has established the right to judgment with such clarity so as to leave no room for controversy. Woods v. Rhodes, 994 F.2d 494, 499 (8th Cir. 1993); Vacca v. Viacom Broadcasting of Mo., Inc., 875 F.2d 1357, 1339 (8th Cir. 1989); *see also* Paragon at 1185 ("summary judgment is authorized when it is quite clear what the truth is").

II. DETERMINATIONS OF VALIDITY UNDER 35 U.S.C. § 102.

Mallinckrodt has asserted that claims 1, 3, 4 and 8 of the '371 Patent are invalid under 35 U.S.C. § 102(b).

U.S. patents are accorded a presumption of validity. 35 U.S.C. § 282. To prove invalidity under 35 U.S.C. § 102(b), Mallinckrodt must show that one or more stated requirements were not met. This Code section states in relevant part that:

A person shall be entitled to a patent unless -

(b) The invention was . . . described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for a patent in the United States,

U.S.C. § 102(b) (emphasis added).

As is apparent from the specific language of the Code, the application of this section requires a specific determination of the "date of the application for a patent." When dealing with CIP applications, this determination can be complex.

III. CONTINUATION-IN-PART APPLICATIONS.

A CIP application contains subject matter from a prior application and may contain additional matter not disclosed in the prior application. "A CIP application can be entitled to different . . . [filing dates] for different claims. Claims containing any matter introduced in the CIP are accorded the filing date of the CIP application. However, matter disclosed in the parent application is entitled to the benefit of the filing date of the parent application." Waldemar Link v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994).

A. Determination of CIP Application's Filing Date.

The plain fact that a CIP application was filed is not determinative that the application contained new matter.⁶ See, Waldemar, 32 F.3d at 559 (Mere filing of a CIP is not a concession that the parent application contained an insufficient disclosure.)

⁶ A CIP application can be filed for numerous reasons. "Such an application may for example contribute a 'mere embellishment or technical improvement of a feature disclosed in the original application, which does not contribute to its novelty, utility or non-obviousness' or may merely elaborate on the disclosures of earlier applications." Hughes Aircraft Co. v. United States, 640 F.2d 1193, 1198 (Ct. Cl. 1980) (quoting Acme Highway Products Corp. v. D.S. Brown Company, 431 F.2d 1094, 1080 (6th Cir. 1970), *cert. denied*, 401 U.S. 956, 91 S.Ct. 977, 28 L.Ed.2d 239 (1971)), and see Azoplate Corp. v. Silverlith, Inc., 367 F.Supp. 711, 732 (D.Del. 1975), *aff'd* 506 F.2d 1050 (3d Cir. 1974), *cert. denied*, 421 U.S. 914, 95 S.Ct. 1572, 43 L.Ed.2d 780 (1975).

The assessment of validity under 35 U.S.C. § 102(b) of a patent issued from a CIP application, therefore, requires a determination of each claim's filing date. The principles for determining the filing date of claims contained in a CIP application are outlined in 35 U.S.C. § 120. This section states:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120.

B. Disclosure Under 35 U.S.C. § 112.

To qualify as a "disclosure" -- and thereby enjoy the benefit of the prior filing date -- the prior application must satisfy the requirements of 35 U.S.C. § 112 first paragraph. This paragraph states as follows:

The specification shall contain a *written description of the invention*, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable* any person skilled in the art . . . to make and use the same

35 U.S.C. § 112, ¶ 1.

In summary, the first paragraph of 35 U.S.C. § 112 requires an adequate written description of the invention -- a description which would enable one skilled in the art to make and use the invention. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

The requirement for a "written description of the invention" is separate and distinct, however, from the enablement requirement.

1. Written description requirement.

The test for sufficiency of the written description in a parent application "is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." Wang Laboratories v. Toshiba Corp., 993 F.2d 858, 865 (Fed. Cir. 1993) (quoting, Vas-Cath, Inc. at 1563).

The issue of whether a parent specification adequately describes the subject matter claimed is a question of fact. In re Alton, 76 F.3d 1168, 1171-72 (Fed. Cir. 1996) (citing Vas-Cath, Inc. at 1563). Specifically, "compliance with the written description aspect . . . is a question of fact" Waldemar Link at 558 (citing Unter v. Hiraaga, 845 F.2d 993, 998 (Fed. Cir. 1988)).

2. Enablement requirement.

Similarly, satisfaction of the enablement requirement also involves questions of fact. See, In re Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991). ("Enablement . . . is a question of law which we independently review, although based upon underlying factual findings which we review for clear error.")

C. Summary Judgment is Inappropriate When The Filing Date of a CIP Application Is At Issue.

Both the written description requirement and the enablement requirement involve questions of fact. Consequently, when a genuine dispute of fact arises regarding the filing date

of claims in a CIP application, summary judgment is inappropriate.' See, Vas-Cath, Inc. at 1567 (summary judgment award reversed because issues regarding the written description requirement gave rise to genuine issues of material fact). See also H. B. Fuller Co. v. National Starch & Chemical Corp., 595 F.Supp. 622, 624 (D. Del. 1984) (the issue of whether a parent application discloses the invention claimed in a CIP application is "highly technical and subject to competing interpretation . . . In other words, there are key factual issues yet to be resolved after a full consideration of the evidence and summary judgment must thus be denied."); Max Daerwyler Corp. v. Input Graphics, Inc., 608 F.Supp. 1549 (E.D. Penn. 1985) (motion in limine denied because it was impossible to conclude as a matter of law that a later application was not entitled to the benefit of the filing dates of earlier applications).

IV. THE CLAIMS AT ISSUE ARE NOT BARRED.

The activities giving rise to Mallinckrodt's Motion for Partial Summary Judgment occurred on October 14, 1989. The "critical date" for purposes of 35 U.S.C. § 102(b) is, therefore, October 14, 1990. For an inventor to be entitled to a patent covering subject matter

⁷ In this case, the issue already is before the Patent Office. On June 5, 1996 AMI filed an application for reissue of the '371 Patent. See Affidavit of Robert M. Rauker attached to the July 2, 1996 letter from Jake M. Holdreith to the Court. This application requested reissue without limitation of the term "self-erecting". In the reissue application, AMI revealed the October 1989 disclosure, placing all relevant information before the Patent Examiner. As allowed by Patent Office rules (37 CFR § 1.11(b)), any other parties, including Mallinckrodt, may submit all information deemed relevant to the patentability of the reissue application. AMI previously requested that the Court continue its decision on Mallinckrodt's partial summary judgment motion pending the decision of the Patent Examiner. See July 2, 1996 letter of Jake M. Holdreith requesting stay of the present motion. The Court denied AMI's request by an order dated June 12, 1996. AMI respectfully submits that allowing the Patent Office to consider this issue would enhance judicial economy because the PTO's decision could (1) moot the Motion if the patent is invalidated based on the issues raised by Mallinckrodt in the present Motion, or in the alternative (2) provide the Court with guidance as to whether the disputed claims were adequately described in the parent application.

disclosed at the 1989 ASA meeting, an application for patent must have been filed prior to October 14, 1990 (the "critical date").

The parent application and all previous related applications were filed prior to the critical date.⁸ As the '371 Patent is entitled to enjoy the benefit of a filing date no later than that of the parent application, the claims at issue were also filed before the critical date.

A. COMPARISON OF '748 APPLICATION AND PARENT APPLICATION.

A comparison of the '748 application and its parent reveals that much of the text contained in the '748 application is also disclosed in the parent application. More importantly, the invention of the claims at issue was sufficiently disclosed in the parent application to inform an "artisan that the inventor had possession at that time of the later claimed subject matter." See Wang at 865. Therefore, the claims at issue have a filing date no later than the filing date of the parent application -- July 10, 1990.

A detailed comparison of these two applications reveals that text was added to and/or changed in the '748 application (and consequently, the '371 patent) at only the following places:⁹

The abstract was rewritten;

Figures 8 through 11 were added;

⁸ As the parent application and all preceding applications were filed prior to the critical date, this Memorandum will discuss only relation back to the parent application. A more thorough review of the '371 Patent history will reveal that certain subject matter contained in the application is entitled to the benefit of the filing date of the great-grandparent application (October 5, 1987). AMI only need show that the claims at issue are entitled to the benefit of the filing date of the parent application to defeat Mallinckrodt's Motion.

⁹ For the convenience of the Court, Exhibit B of the Lervick Affidavit includes a copy of the '371 Patent in which all text added to a specification in the '748 application has been highlighted. All of the text which is not highlighted relates back to the July 10, 1990 filing date of the parent application.

Text was added at column 1, line 59 through column 2, line 2;

At column 2, line 4, "method therefor" was added;

Text was added at column 2, lines 21 through 27, lines 44 through 46, and lines 49 through 51;

At column 3, line 8, "patient's head and face" was replaced with --care site--;

At line 13 --legs and/or-- was added;

Text was added at column 3, lines 18 through 21 and lines 49 through 60; and

Text was added at column 8, line 32 through column 11, line 3; and at column 11, lines 5 through 9.

All other text in the '748 application was included in the parent application.

B. THE PARENT APPLICATION PROVIDES AN ADEQUATE DISCLOSURE.

The disclosure in the parent application reasonably conveys to one skilled in the art that the inventor had possession at the time of the claimed subject matter. In opposition to Mallinckrodt's Motion, AMI has filed herewith the Affidavit of Daniel N. Campau. As set forth in Mr. Campau's Affidavit, the parent application reasonably conveys to one skilled in the art that the inventors had possession of the subject of the disputed claims. See Affidavit of Daniel M. Campau ("Campau Aff.") (indicating that all the claims at issue are sufficiently disclosed in the parent application). Consequently the claims at issue are entitled to the filing date of the parent application. See Yas-Cath, Inc. at 1553 (restating the test for the written description requirement).

A. Claim 1 is sufficiently disclosed in the parent application.

Claim 1 is directed toward a thermal blanket for covering and bathing a portion of a patient's body from the pelvic area to the feet in a thermally controlled inflating medium. Claim 1 specifically states:

1. In a self-erecting inflatable thermal blanket for covering and bathing a portion of a patient's body in a thermally-controlled inflating medium, the improvement comprising:
 - a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;
 - an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;
 - said inflatable chambers in said covering for substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body;
 - a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chamber; and
 - a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet.

Exhibit B to the Lervick Affidavit at column 11, lines 14-38.

The disclosure in the parent application clearly indicates that the thermal blanket has a flexible base sheet with a head end, foot end and two edges (see Exhibit A to the Lervick Affidavit (parent application) at p. 10 and at figs. 1, 2 & 4) and a plurality of apertures (see *Id.* at p. 7). The disclosure describes the blanket to have an overlying flexible material sheet (see *Id.* at p. 11) which are attached to the flexible base sheet by a plurality of discontinuous seams (see Exhibit A to the Lervick Affidavit at p. 9). The parent disclosure indicates the formation of a plurality of communicating inflatable chambers (see *Id.* at p. 9). The parent application discloses substantial longitudinal disposition over the patient's body (see *Id.*, Figures 1 through 7). A

continuous seam near the head end also is disclosed in the parent application (see *Id.* at p. 9). Lastly, the specification of the parent application discloses a non-inflatable section substantially between the continuous seam and said head end (see *Id.* at p. 8).

In addition to the above-cited references, the parent application makes numerous statements indicating that the blanket can be positioned on the patient's body at various places. As indicated by expert Campau, the parent application recognizes that care sites must be visible and clean. Campau Affidavit at 2. A care site, of course, can exist at numerous places on a patient's body. The parent application also indicates that the viewing recess permits observation of the patient's head, face, neck and chest from any location. Exhibit A to Lervick Affidavit (parent application) at 8. This suggests that the blanket can be appropriately positioned to accommodate whatever viewing requirements are necessary. For example, the disclosure indicates that the blanket can be drawn up to the patient's chin. *Id.* at p. 10. As confirmed by expert Campau, this reveals that the blanket can be positioned variously on the patient's body. One variation of such positioning could cover the patient from the pelvic area to the feet. Campau Affidavit at p. 2.

The subject matter claimed in claim 1 was sufficiently disclosed in the parent application. Claim 1, therefore, is clearly entitled to the filing date of the parent application.

B. Claim 3 is sufficiently described in the parent application.

Claim 3 of the '371 Patent is dependent upon claim 1. This claim further adds the concept of including an attachment means to the head end of the blanket.¹⁰ Use of an attachment

¹⁰ Claim 3 of the '371 Patent states as follows:

means in combination with the blanket described in claim 1 is also sufficiently disclosed in the parent application.

As recognized by expert Campau, "the absorbent bib...acts...to seal the head end of the inflated structure." Exhibit A to the Lervick Affidavit (parent application) at pp. 3-4. This information "clearly contemplates the use of other means to provide the requisite seal." Campau Affidavit at 2. Alternatively stated, the disclosure in the parent application sufficiently discloses the invention of claim 3.

C. Claim 4 is sufficiently described in the parent application.

Similar to claim 1, claim 4 relates to an inflatable thermal blanket while covering and bathing a portion of a patient's body. In claim 4, however, the blanket is positioned across the arms and chest of a patient's body. More specifically, claim 1 states:

4. In a self-erecting inflatable thermal blanket for covering and bathing a portion of a patient's body in a thermally-controlled inflating medium, the improvement comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

said inflatable chambers for substantially transverse disposition over a portion of said patient's body and extending substantially across the arms and chest of said patient's body;

a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers; and

3. The improvement of claim 1 further including an attachment means at said head end for adhering said head end to said pelvic area and preventing migration of air from under said thermal blanket toward a care site.

Exhibit B to Lervick Affidavit, column 11, lines 42-45.

a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet.

Exhibit B to the Lervick Affidavit, column 11, lines 46-68.

The elements of claim 4 are disclosed sufficiently in the parent application reasonably convey to an artisan that the inventor had possession at the time of filing of the subject matter claimed. The Disclosures of the parent application includes the following:

Claim 4 first requires a flexible base sheet. This flexible base sheet appears in the Parent application at p.10 (see Exhibit A to the Lervick Affidavit (parent application) at p. 10). The flexible base sheet is said to have a plurality of apertures therein. The apertures are disclosed in the parent application. Exhibit A to the Lervick Affidavit (parent application) at p. 7.

Next, the second paragraph of claim 4 requires an overlying flexible material sheet. This overlying flexible material sheet is disclosed at p. 11. See Exhibit A to the Lervick Affidavit (parent application) p. 11. Claim 4 also requires that the overlying flexible material sheet be attached to the base sheet by a plurality of discontinuous seams. The disclosure of discontinuous seams is found in the parent application. *Id.* at p. 9. Claim 4 states that attachment of a base sheet by a plurality of discontinuous seams forms said overlaying material sheet into a plurality of communicating inflatable chambers. The production of communicating inflatable chambers is also disclosed. *Id.*

Claim 4 then states that the inflatable chambers are transversely disposed over a portion of the patient's body extending across the arms and chest. As indicated by expert Campau, the applicants revealed that the blanket could be repositioned at numerous locations over the patient's body. Campau Affidavit at pp. 2-3. Furthermore, claim 4 requires that the inflatable chambers be transversely disposed over a patient's body. Figures 1 and 2 of the parent

application clearly show the array of chambers situated transverse to a patient's body. See Exhibit A to the Lervick Affidavit (parent application), Figures 1 and 2. The claim does not require that a single chamber run transverse to the patient's body. Consequently, the claim is not limited to a specific alignment of the inflatable chambers. Furthermore, the parent application clearly indicates that structures other than tubes shown in Figures 1 through 6 could be used. See, Campau Affidavit at p. 3, and Exhibit A to the Lervick Affidavit (parent application) at p. 8. The tubes, therefore, can run different directions than those specifically revealed.

The combination of these numerous concepts clearly indicates that the inventor at the time of filing the parent application had in his possession the claimed subject matter.

Next, claim 4 requires a continuous seam near the head end. Such a continuous seam is clearly shown in the parent application at p. 9. See Exhibit A to the Lervick Affidavit (parent application) at p. 9).

Lastly, claim 4 in the final paragraph requires a non-inflatable section extending between the continuous seam and the head end. Once again, this description was clearly shown in the parent application. See Exhibit A to the Lervick Affidavit (parent application) at p. 8.

The parent application sufficiently discloses the subject matter claimed in claim 4. Consequently, this claim is also entitled to the benefit of a filing date no later than that of the parent application.

D. Claim 8 is entitled to the filing date of the parent application.

Claim 8 is directed toward an embodiment of the invention which is placed across the arms and chest of the patient's body. Specifically, claim 8 states:

8. An inflatable thermal blanket for convectively controlling the temperature of a portion of a patient's body, comprising:

a self-erecting inflatable cover with an undersurface and a plurality of substantially elongate, inflatable chambers for substantially transverse disposition over a portion of a patient's body and extending substantially across the arms and chest of said patient's body;

an inflating inlet for admitting a thermally-controlled inflating medium into said chambers for erection of said inflatable covering;

an array of apertures in said undersurface for exhausting a thermally-controlled inflating medium from said chambers through said undersurface to a space between said undersurface and said patient's body;

a first recess in said inflatable chambers extending across and closing off first inflatable chambers adjacent a first peripheral margin of said inflatable covering;

a second recess in said inflatable chambers extending across and closing off second inflatable chambers adjacent a second peripheral margin of said inflatable covering opposite said first peripheral margin;

the second recess for accommodating the curvature of said patient's torso; and

attachment means at said second recess for adhering said inflatable covering to said chest and preventing migration of air from underneath said thermal blanket toward a care site.

Exhibit B to the Lervick Affidavit, column 12, lines 11-39.

The invention claimed in claim 8 is disclosed in the parent application. This conclusion is affirmed by expert Campau. See Campau Affidavit at p. 1. Claim 8 is therefore also entitled to the benefit of the filing date of that application.

The first paragraph of claim 8 recites an inflatable cover with a plurality of elongate inflatable chambers. An inflatable covering with inflatable chambers is clearly disclosed in the parent application. See Exhibit A to the Lervick Affidavit (parent application) at p. 11. This paragraph also requires the chambers be substantially transversely disposed over a portion of the patient's body and extending across the arms and chest of the patient. As detailed regarding

claim 4, the applicant, in the parent application, clearly disclosed this possibility. All elements of this paragraph are disclosed in the parent application.

The next paragraph of claim 8 requires an inflating inlet. The inflation inlet or inflation inlet cuff is shown which accommodates the inflation of the blanket. See Exhibit A to the Lervick Affidavit (parent application) at p. 7.

The next paragraph of claim 8 requires that the undersurface of the inflatable cover has an array of apertures. These apertures are disclosed in the parent application at page 7. Exhibit A to the Lervick Affidavit (parent application) at 7.

In the next two paragraphs, a first recess and a second recess, extending across and closing off inflatable chambers are required. Page 8 of the parent application (Exhibit A to the Lervick Affidavit) clearly shows the existence and use of a recess. Furthermore, Figures 1, 2 and 5 all show a recess in the blanket's configuration. See also Campau Affidavit at p. 3. Consequently, the use of a recess or recesses were clearly contemplated by the applicants at the time of the parent application.

The next paragraph states that the second recess is for accommodating the curvature of a patient's torso. As previously stated, the use of a recess was clearly contemplated by the inventors at the time of filing the parent application. See Campau Affidavit at p. 3. Additionally, the placement of the blanket at numerous places on the patient's body is disclosed. Therefore, this concept was sufficiently disclosed in the parent application.

The description in the parent application sufficiently discloses to an artisan that the invention claimed in claim 8 was within the inventor's possession. Claim 8 is entitled to the benefit of a filing date no later than July 10, 1990.

CONCLUSION

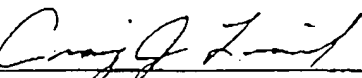
Mallinckrodt has failed to establish by clear and convincing evidence that the parent application does not reasonably convey to the artisan that AMI had possession of the subject matter of claims 1, 3, 4 and 8 of AMI's patent 5,405,371. Mallinckrodt, in fact, has not even addressed the issue of whether the elements of the claims at issue were adequately disclosed in the July 10, 1990 application. As noted by the Federal Circuit, a determination of whether subject matter provides a clear description to an artisan is inherently unsuitable for summary judgment. The question of whether — in the eyes of a person skilled in the art — the disclosures in the parent, grandparent or great-grandparent applications were sufficient should be left to the jury.

Summary judgment should be denied.

Date: July 17, 1996

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ATTORNEYS FOR PLAINTIFF
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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
FOURTH DIVISION

AUGUSTINE MEDICAL, INC.,

Plaintiff,

v.

MALLINCKRODT GROUP INC. and
MALLINCKRODT MEDICAL, INC.,

Defendants.

Civil Action No. 4-94-CV-875

DEFENDANTS' REPLY TO
MEMORANDUM OF AUGUSTINE
MEDICAL, INC. IN OPPOSITION
TO DEFENDANTS' MOTION FOR
PARTIAL SUMMARY JUDGMENT

INTRODUCTION

Plaintiff Augustine Medical, Inc.'s ("AMI's") Memorandum in Opposition to Defendants' Mallinckrodt Group Inc.'s and Mallinckrodt Medical, Inc.'s (collectively "MMI's") Motion for Partial Summary Judgment of Invalidity of U.S. Patent No. 5,405,371 (the "'371 Patent"), does not dispute the fact that the subject matter of claims 1, 3, 4 and 8 of that Patent was described in a printed publication, and was publicly used and placed on sale by virtue of AMI's 1989 Activities.¹ Rather, AMI only makes the legal argument that the subject matter of the claims at issue was sufficiently described and enabled by an earlier parent application (Serial No. 550,757, the "Parent Application"), such that the claims are entitled to the filing date of that earlier application.² AMI takes this position despite the

¹The meanings of the defined terms used in MMI's Motion for Partial Summary Judgment of Invalidity of Claims 1, 3, 4 and 8 of U.S. Patent No. 5,405,371 ("MMI's Motion") are incorporated herein by reference. AMI's Memorandum in Opposition to Motion for Partial Summary Judgment is hereinafter referred to as "AMI's Opposition."

²The filing date of the Parent Application is July, 1990. Accordingly, if the subject claims were given this filing date, the October 1989 Activities would, by approximately three months, not be a statutory, § 102(b) bar to the patentability of the claims.

fact that when it filed its continuation-in-part application which resulted in the '371 Patent (the "CIP Application"), it rewrote the Abstract in the CIP Application to change the focus of the application to blankets which only cover a portion of a body, such as the legs or arms, and added more than three columns of written description and four figures specifically describing and showing the upper and lower body blankets of the claims at issue. The modifications of and additions to the text and Figures in the CIP Application belie AMI's litigation-induced position that the subject claims were sufficiently described and enabled by the Parent Application. AMI's arguments fall under their own weight and are nothing more than a desperate attempt to salvage patent claims which are clearly invalid in view of AMI's own admissions regarding its 1989 Activities.

The weakness of AMI's position is perhaps best exemplified by the very Affidavit which AMI proffers to support its position, namely, the Affidavit of Daniel N. Campau ("Campau Affidavit"). As discussed more fully below, in order to prevail in its opposition to MMI's Motion, AMI must show that a reasonable fact finder could conclude that the Parent Application would "convey with reasonable clarity" to those of skill in the art that AMI was "in possession of the invention of claims 1, 3, 4 and 8 and that one reading the specification of the Parent Application "would immediately discern" the claim limitations at issue. Far from meeting these standards, the Campau Affidavit shows that there was not even a hint of the lower and upper body blankets of claims 1, 3, 4 and 8 in the Parent Application, much less any description which would "convey with reasonable clarity" or enable one to "immediately discern" the claimed subject matter.

As is clear from the Campau Affidavit itself, and as is described in more detail below, there is no genuine dispute that the subject matter of the claims at issue was not sufficiently

described and enabled in the Parent Application and no reasonable jury could find that the '371 Patent is not invalid.

ARGUMENT

The standard for summary judgment provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact. See *Paragon Podiatry Laboratory v. KLM Laboratories*, 984 F.2d 1182 (Fed. Cir. 1993) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986)) (emphasis original). The proper inquiry, therefore, is whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law. *Id.* In this case, it is clear from the '371 Patent and the Parent Application, that the claims at issue are not entitled to the filing date of the Parent Application because there is no written description of the subject matter of those claims in the Parent Application so as to enable a person skilled in the art to make and use the invention, as required under 35 U.S.C. § 112.

For a later filed application to be entitled to the benefit of the date of a previously filed application, the previously filed application must contain a written description of the invention which complies with the requirement of the first paragraph of 35 U.S.C. § 112. In order to meet the written description requirement of § 112, the description in the patent application must clearly allow person(s) of ordinary skill in the art to recognize that the applicant invented what is claimed. That is, the applicant must "convey with reasonable clarity" to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. See *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996). It must

be determined whether one reading the specification of the earlier application "would immediately discern" the claim limitations at issue. See *Waldemar Link v. Osteonics Corp.*, 32 F.3d 556, 558 (Fed. Cir. 1994).

The issue of whether an application satisfies the requirements of 35 U.S.C. § 112, first paragraph, is a question of law based on underlying issues of fact (the issue of whether a patent specification meets the written description requirement under § 112 involves questions of fact). *Id.* Accordingly, as with all motions for summary judgment, where there is no genuine dispute as to issues of material fact, summary judgment is appropriate.³ The present case is just such a case.

There Is Nothing In The Parent Application Which In Any Way Indicates That AMI Was "In Possession Of" The Later Claimed Subject Matter

Although the Campau Affidavit conclusorily states that the parent application "reasonably conveys" the subject matter of the claims at issue, that statement is not supported by any logical interpretation of the Parent Application and '371 Patent specification. The Affidavit does not (because it cannot) reference any portion of the Parent Application that specifically describes the subject matter of the claims. Rather, the Campau Affidavit almost exclusively relies on vague allegations that the subject matter of the claims

³AMI's bare assertion in its Opposition at 9, that "summary judgment is inappropriate when the filing date of a CIP application is at issue" is wrong. The sufficiency of the disclosure in a parent application with respect to the requirements of § 112 must be determined on a case-by-case basis. *Eiselstein v. Frank*, 52 F.3d 1035, 1039-40 (Fed. Cir. 1995) (where the court found claims directed to a range of nickel content in an alloy of "from about 45% to about 55% of the alloy" to be sufficiently described under § 112 by the specification which described a "nickel in a weight proportion of 45% to 55% of the alloy," but did not find claims reciting a balance "with nickel constituting about 50 to about 60% of the alloy" to be sufficiently described by the specification). Though in certain circumstances, there may be questions of fact involved in determining whether an application meets the requirements of § 112, the ultimate conclusion is one of law (similar to an infringement analysis) and is subject to the well-known and often quoted "genuine issue of material fact" standard. See *Anderson*, 477 U.S. at 247-248.

is "inherent" in the teachings of the Parent Application. However, the loose and expansive use of the term "inherent" in the Campau Affidavit and in AMI's Opposition is a misapplication of the legal standard under § 112 and highlights the deficiencies in AMI's position.⁴

Moreover, even if principles of inherency were appropriate here (although, in actuality they are not), the doctrine of inherency is necessarily limited by the description requirement of § 112 and the party relying on inherency bears the burden of proving that the disclosure of the parent application would necessarily lead one skilled in the art to the claimed subject matter. See *Wagner v. Barger*, 463 F.2d 1377 (C.C.P.A. 1972). The fact that later disclosed material might have been surmised from the earlier application is insufficient. See *Fox Indus., Inc. v. Structural Preservation Systems, Inc.*, 6 U.S.P.Q.2d 1577, 1590 (D. Md. 1988); 4 Chisum Patents, § 13.04[4] at 13-32. AMI's Opposition and the Campau Affidavit do not on their face meet the standard required by § 112 and, therefore, AMI's Opposition raises no genuine issue of material fact. The specifications of the Parent Application and the '371 Patent are so starkly contrary to the conclusory statements in the Campau Affidavit that the Affidavit should be given no weight.

⁴Principals of inherency in the context of sufficiency of disclosure are generally applied where a claim element and patent specification describe a property of a structure, albeit in arguably varying terms (e.g., the claim recites an elastomer of a "low crystallization type" and the specification describes an elastomer "with high resistance to sunlight and pavement erosion," see *Acme Highway Prod. Co. v. D. S. Brown Co.*, 431 F.2d 1074 (6th Cir. 1970)). The question then becomes whether one of skill in the art would immediately recognize that the specification necessarily described the claimed property of the structure. Such principles are not applicable in this case where AMI attempts to read into the Parent Application whole devices and parts of devices which simply are not there. See also *Mendenhall v. Cedarapids, Inc.*, 28 U.S.P.Q.2d 1081, 1088-89 (Fed. Cir. 1993).

Claim 1, Directed To A Lower Body Blanket, Is Not Described Or Enabled By The Parent Application

There is absolutely no written description in the Parent Application of the following subject matter of claim 1 of the '371 Patent.⁵

a "self-erecting inflatable thermal blanket for covering and bathing a portion of a patient's body in a thermally-controlled inflating medium;"

inflatable chambers in the covering "for substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body; and

"a non-inflatable section . . . extending substantially between" the continuous seam and the head end of the blanket.

Rather, the lower body blanket of claim 1 is described only in the new material added to the specification of the '371 Patent when the CIP Application was filed on January 8, 1991. For example, under the Summary of the Invention, the following language was added on January 8, 1991:

Finally, we have observed that our self-erecting air flow cover may be advantageously adapted to thermally control specific partial portions of the patient such as the legs and lower body or the arms and upper body leaving other areas of the patient available for care and treatment.

Column 1, lines 59-64. The lower body blanket is more fully described in the '371 Patent at column 8, line 32 - column 9, line 44, and in Figs. 8 and 9. All of this written description, including Figs. 8 and 9, represents material that was added in the CIP Application filed on January 8, 1991. Prior to that date, there is not a single word in the Parent Application of a blanket designed to cover only a portion of a patient's body, much less the legs or lower body as recited by claim 1.

⁵For sake of brevity, MMI only discusses the elements of the subject claims of the '371 Patent which are glaringly absent from the Parent Application.

AMI does not argue, because it cannot, that a written description of the subject matter of claim 1 is expressly contained in the specification of the '371 Patent. Rather, AMI asserts in its Opposition at 14 that the Parent Application makes statements "indicating" that the blanket "could be" positioned on the patient's body at various places," and "suggests" that the blanket "can be" appropriately positioned to accommodate whatever viewing requirements are necessary. AMI's assertions, even if correct, do not meet the legal test under the written description and enablement requirements of § 112. *See, e.g., Wagner*. Even under principles of inherency, the party asserting that later filed claims are entitled to the filing date of an earlier parent application bears the burden of proving that the disclosure of the parent application would necessarily, not "might," lead one skilled in the art to the claimed subject matter, and AMI makes no such assertion. *See Wagner*.

Further, AMI's assertions are not supported by the specification of the Parent Application and are patently unreasonable. For example, AMI asserts in its Opposition at 14 that, "The Parent Application makes numerous statements indicating that the blanket can be positioned on the patient's body at various places." However, AMI's Opposition provides no support for this statement. This is because there is no support to be found in the Parent Application.

AMI also asserts in its Opposition at 14 that the Parent Application recognizes that "care sites" must be kept visible and clean (citing Campau Affidavit at 2), and then urges that "A care site, of course, can exist at numerous places on a patient's body." However, the only reference to "care site" in the portions of the Parent Application cited at p. 2 of the Campau Affidavit (i.e., pp. 4-5 of the Parent Application), specifically indicates only a "care site in the vicinity of the patient's head and face." Parent Application at 5. Even more importantly, it is extraordinary, to say the least, that AMI can assert in good faith that the

Parent Application's reference to "means for maintaining the cleanliness of the care site in the vicinity of the patient's head and face" in any way supports, much less, allows one to "immediately discern" the claimed subject matter directed to a self-erecting inflatable blanket covering a "portion" of a patient's body and having chambers for "substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body."

Equally extraordinary (yet indicative of the weakness of AMI's Opposition) is AMI's reliance on the statement in the Parent Application that "the blanket can be drawn up to the chin area so that the absorbent bib can be placed laterally up the neck of the patient," to support AMI's assertion that the lower body blanket of claim 1 is "inherently" described in the specification of the '371 Patent. AMI Opposition at 14; Campau Affidavit at 2. Query, how does the statement that "the absorbent bib can be drawn up to the chin of a patient" allow one to "immediately discern" the claimed invention of a lower body blanket? AMI's position is patently nonsensical.

As can be seen from the Summary of the Invention portion of the '371 Patent which was added when the CIP Application was filed in January of 1991, AMI described its "invention" as a "self-erecting air-flow cover that may be advantageously adapted to thermally control specific partial portions of the patient such as the legs and lower body or the arms and upper body leaving other areas of the patient available for care and treatment." Column 1, lines 59-64 (emphasis added). AMI's reliance on an assertion that "care sites must be visible and clean," or that the "absorbent bib can be drawn up to the chin area" suggest nothing about the lower body airflow cover of claim 1 which is described in the Summary of the Invention as "advantageously adapted to thermally control specific partial portions of the patient such as the legs and lower body."

In sum, no reasonable jury could find that the Parent Application's reference to "means for maintaining the cleanliness of the care site in the vicinity of the patient's head and face" and an absorbent bib with an indent cut into its outside edge which permits the blanket to be drawn up to the chin so that the absorbent bib can be placed laterally up the neck of the patient would permit one to "immediately discern" the limitations of claim 1, namely, a blanket for covering "a portion" of a patient's body "extending substantially from the pelvic area of the patient's body to the feet . . ."

Moreover, although the Campau Affidavit states "if the care site is above the pelvic area it is inherent to limit the extent of the blanket to the region below the care site," there is absolutely nothing in the Parent Application which even suggests limiting the blanket to a region below a care site. The assertion in the Campau Affidavit that "Shorter blankets are contemplated in the '757 application at page 11" is in error as there is no mention of a shorter blanket in the Parent Application. No reasonable jury could find that there is any language in the Parent Application (much less language which "conveys with reasonable clarity") that AMI was in possession of an "invention" of a lower body blanket as of July 1990 when it filed its Parent Application.

Claim 3, Also Directed To A Lower Body Blanket, Is Not Described Or Enabled By The Parent Application

Claim 3 of the '371 Patent depends from claim 1 (and therefore contains all limitations of claim 1) and in addition recites "an attachment means at said head end [of the blanket] for adhering said head end to said pelvic area and preventing migration of air from under said thermal blanket to the care site."⁶ The only mention of any attachment means

⁶Since Claim 1 is unsupported by the Parent Application, Claim 3 is also necessarily unsupported by the parent Application. However, as set forth below, the additional subject matter of Claim 3 is also not described or suggested in the Parent Application.

or structure for adhering the blanket to any portion of the body is in the portion of the specification of the '371 Patent which was added when the CIP Application was filed on January 8, 1991 and shows an adhesive strip (e.g., column 8, line 58 - column 9, line 7). Contrary to AMI's implication in its Opposition at 15, there is no mention whatsoever in the Parent Application of the absorbent bib disclosed in that Application having an adhesive strip or any other means for physically attaching the blanket to the patient.

Here, AMI relies on the statements in the Campau Affidavit at 2 that, "The absorbent bib also acts to some extent to seal the head end of the inflated structure. This clearly contemplates the use of other means to provide the requisite seal." This statement, however, sheds no light on the limitation of claim 3 which recites an attachment means for adhering the blanket to the pelvic area of the patient. First, the Campau Affidavit does not even state that the absorbent bib disclosed in the Parent Application has structure, such as the adhesive strip disclosed in the CIP Application, for attaching the blanket to the body of the patient. Further, the language of the Parent Application quoted in the Campau Affidavit refers to sealing the head end of the inflated structure (not "sealing" the blanket to the body). Moreover, there is no limitation in claim 3 reciting a "requisite seal."

In sum, the unsupported and weak statements in the Campau Affidavit do not meet the legal test under § 112 and show the lack of any genuine disputed issue of fact. No reasonable jury could find that one of skill in the art would "immediately discern" the "attachment means" at the head end of the blanket for "adhering said head end to said pelvic area and preventing migration of from under said thermal blanket towards a care site," from the quoted language in the Parent Application regarding the absorbent bib.

Claim 4, Directed To An Upper Body Blanket, Is Not Described Or Enabled By The Parent Application

AMI's assertions that the Parent Application contains a written description of an upper body blanket for "covering and bathing a portion of a patient's body" and having "chambers for substantially transverse disposition over a portion of said patient's body and extending substantially across the arms and chest of said patient's body" as required by claim 4 of the '371 Patent, are frivolous. There is no hint in the Parent Application of a blanket that covers only a portion of a patient's body (here, only the arms and chest), as explained above, and there is no hint in the Parent Application of a blanket with chambers transversely disposed over and extending across the arms and chest of the patient. Rather, the written description supporting the subject matter of claim 4, namely, an upper body blanket, is described in the '371 Patent at column 9, line 45 - column 11, line 12; the upper body blanket including the transversely disposed chambers extending across the arms and chest of the patient is shown in Figs. 10 and 11 - all of which description was added when the CIP Application was filed on January 8, 1991.

The statement in the Campau Affidavit at 2-3 that AMI was "aware that the blanket could be positioned in many ways," is notable only in that it is not supported by any citation to the Parent Application (because neither that statement nor any statement to that effect is contained in the Parent Application). Also, one cannot discern what the statements in the Campau Affidavit at 3 regarding "various patterns of communicating chambers" or by virtue of an indent in the absorbent bib "the blanket could be drawn up to the patient's chin if needed to provide absorbency laterally up the neck of the patient," have to do with a blanket for bathing a "portion" of a patient's body having "inflatable chambers for substantially transverse disposition over" and "extending substantially across the arms and chest" of the

patient, as recited in claim 4: The chambers disclosed in the CIP Application for the upper body blanket are in an elongated "tube" pattern (i.e., the issue of various patterns does not apply); however, they run perpendicular (i.e., transverse) to the trunk of the patient's body and extend only across the arms and chest of the patient. This subject matter is clearly not described in the Parent Application.

AMI also urges that Figs. 1 and 2 of the Parent Application show an "array of chambers situated transverse to a patient's body," AMI's Memorandum at 17. There is no statement to that effect in the Campau Affidavit, and in any event, AMI does not assert (because it cannot) that any of the Figures in the Parent Application describe or show chambers "for substantially transverse disposition" "extending substantially across the arms and chest of said patient's body" as required by claim 4. In sum, AMI has come forward with absolutely no evidence that it was in possession of an invention relating to an upper body blanket when it filed the Parent Application and no reasonable jury could find that one reading the specification of the Parent Application "would immediately discern" the subject matter of claim 4.

Claim 8, Also Directed To An Upper Body Blanket, Is Not Described Or Enabled By The Parent Application

There is also no hint in the Parent Application of the following subject matter of claim 8 of the '371 Patent.

"An inflatable thermal blanket for convectively controlling the temperature of a portion of a patient's body;"

"a self-erecting inflatable cover with an undersurface and a plurality of substantially elongate, inflatable chambers for substantially transverse disposition over a portion of a patient's body and extending substantially across the arms and chest of said patient's body;"

"a first recess in said inflatable chambers extending across and closing off first inflatable chambers adjacent a first peripheral margin . . .," and "a second

recess in said inflatable chambers extending across and closing off second inflatable chambers adjacent a second peripheral margin . . . opposite said first peripheral margin," the second recess "for accommodating the curvature of the patient's torso;" and

"attachment means at said second recess for adhering said inflatable covering to said chest and preventing migration of air from underneath said thermal blanket toward a care site."

As explained above, there is nothing in the Parent Application describing or referring to a blanket which covers only the patient's arms and chest with chambers disposed transversely over and extending across the arms and chest.

As to the other elements of claim 8, AMI urges in its Opposition at 19 that the use of a recess at the patient's chin as shown in Figs. 1, 2 and 5 of the Parent Application constitutes a written description of the first and second recesses recited in claim 8. It is quite clear, however, from a review of the Parent Application that the one recess shown in Figs. 1, 2 and 5 is for enabling viewing of the head, Parent Application at 10, (not the torso). AMI can point to no language in the Parent Application which even suggests a second recess opposite a first recess, much less a second recess "for accommodating the curvature of the patient's torso" as recited in claim 8. There is also no mention or suggestion in the Parent Application, as explained above, of an attachment means (such as an adhesive strip) at the second recess for adhering the blanket to the patient as required by claim 8.

In support of AMI's assertions with respect to the "attachment means" of claim 8, the Campau Affidavit states:

The need for a second recess across the patient's torso follows from the teaching of the '757 application at p. 8 which calls for "a non-inflated blanket recess . . . which remains smooth and flat when the blanket is inflated and erected." It follows that this recess which accommodates the patient's torso allows the covering to be adhered to the patient's chest.

The statement is nonsensical on its face. The "non-inflated blanket recess" referenced in the Parent Application is at the chin area and does not "accommodate the patient's torso." The statement also ignores the requirement of structure for attaching the blanket (i.e., "attachment means") to the patient at the second recess.

CONCLUSION

AMI's Opposition is unsupported and insupportable. AMI is obviously grasping at straws to attempt to avoid invalidation of the '371 Patent claims at issue. The fact of the matter, of course, is that AMI invalidated its '371 Patent when it publicly described, used and placed on sale, its lower and upper body blankets, more than one year before filing for a patent on those blankets. One questions how AMI can seriously contend that the Parent Application in any way provides a written description and enables the subject matter recited in claims 1, 3, 4 and 8 of the '371 Patent, much less that the Parent Application "conveys with reasonable clarity" or allows one of ordinary skill in the art to "immediately discern" the subject matter of the claims. It is, therefore, respectfully urged that summary judgment of invalidity of the '371 Patent is appropriate and entry of partial summary judgment as to that patent is respectfully requested.

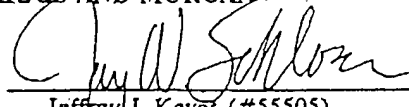
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COUNTY OF HENNEPIN)

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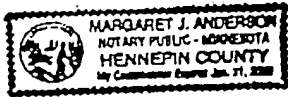
Court File No. 4-94-CV-875

Wanda M. Cotton, being first duly sworn, deposes and states that on the 22nd day of July, 1996, she caused a true and correct copy of the attached Defendants' Reply to Memorandum of Augustine Medical, Inc. in Opposition to Defendants' Motion for Partial Summary Judgment to be served via messenger upon Timothy M. Kenny, Esq., attorneys for plaintiff, at Oppenheimer, Wolff & Donnelly, 3400 Plaza VII Building, 45 South 7th Street, Minneapolis, Minnesota, 55402.

Wanda M. Cotton

Subscribed and sworn to before
me this 22nd day of July, 1996.

Margaret J. Anderson
Notary Public



The USPTO date stamp hereon acknowledges receipt of:

AMENDMENT AND REQUEST FOR RECONSIDERATION for "Thermal Blanket"

Applicant: S.D. Augustine, et al.
Assignee: AUGUSTINE MEDICAL, INC.
Serial No.: 08/419,719
Filed: April 10, 1995

Enclosures: Petition for Extension of Time (2 pgs.) (in dup)

a check for \$465.00

Information Disclosure

PTO Form 1449 (1 pg.)

a check for \$230.00

Terminal Disclaimer (1

a check for \$55.00

Mailed: October 31, 1996
TAM/jiv 1342-119

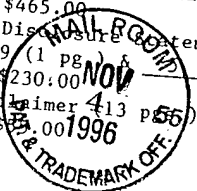
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Enclosures: Petition for Extension of Time (2 pgs.) (in dup)
a check for \$465.00
Information Disclosure Statement (2 pgs. & copy)
PTO Form 1449 (1 pg.)
a check for \$230.00
Terminal Disclaimer (1 pg.)
a check for \$55.00

Mailed: October 31, 1996
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10/31/96	Total paid	55.00
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750 B STREET SUITE 3100 SAN DIEGO, CA 92101

PENINSULA BANK OF SAN DIEGO
SAN DIEGO, CA 92103
90-3482-1222

10/31/96 16291 *****\$55.00

AMOUNT

FIFTY FIVE AND 00/100 DOLLARS

TO THE
ORDER
OF
U. S. P. T. O.

GENERAL ACCOUNT

Thomas A. Aldred

החוקים וההנהגות:

PT000
Vouch
9295

U.S.P.T.O.

Date Description
10/31/96 1342119 EXTENSION OF TIME

Case
1342119

16292
Amount
465.00

10/31/96 Total Paid 465.00

BAKER, MAXHAM, JESTER & MEADOR
A PROFESSIONAL LAW CORPORATION
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PENINSULA BANK OF SAN DIEGO
SAN DIEGO, CA 92103
90-3482-1222

16292

10/31/96 16292 *****\$465.00

AMOUNT

DATE

FOUR HUNDRED SIXTY FIVE AND 00/100 DOLLARS

PAY
TO THE
ORDER
OF

U.S.P.T.O.

GENERAL ACCOUNT

T. Meador

מס' חשבון: 1342119 תאריך: 31/10/96

Security features included. Details on back.

PT000
Vouch
9297

U.S.P.T.O.
Date 10/31/96
Description 1342119 IDS

Case 1342119
16294
Amount 230.00

10/31/96 Total Paid 230.00

BAKER, MAXHAM, JESTER & MEADOR
A PROFESSIONAL LAW CORPORATION
SYMPHONY TOWERS (619) 233-9004
750 B STREET SUITE 3100 SAN DIEGO, CA 92101

PENINSULA BANK OF SAN DIEGO
SAN DIEGO, CA 92103
190-3482-1222

16294

10/31/96 16294 *****\$230.00

AMOUNT

DATE

TWO HUNDRED THIRTY AND 00/100 DOLLARS

PAY
TO THE
ORDER
OF

U.S.P.T.O.

GENERAL ACCOUNT

Terrence H. Baker

Security features included. Details on back.

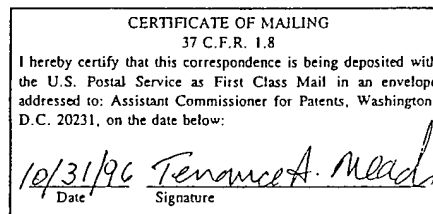
"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
S.D. AUGUSTINE, ET AL.) Group Art Unit: 3304
Serial No.: 08/419,719)
Filed: April 10, 1995) Examiner: M. Graham
For: INFLATABLE LOWER BODY)
THERMAL BLANKET (As Amended))

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:



AMENDMENT AND REQUEST FOR RECONSIDERATION

In response to the Office Action dated May 2, 1996, please amend this application
as follows:

IN THE SPECIFICATION

Page 1, line 8, please insert the following paragraph:

--This application is related to copending U.S. Patent Applications
08/386,324; 08/388,730; and 08/419,718.--

IN THE TITLE

Please amend the title at page 1, line 1 and page 33, line 1 as follows:

INFLATABLE LOWER BODY THERMAL BLANKET

IN THE CLAIMS

Please amend the claims as follows:

- 1 26. (Amended) An inflatable thermal blanket for covering and bathing a
2 portion of a patient's body with thermally-controlled air, comprising:
3 a flexible base sheet having a first end forming a first end of the
4 thermal blanket, a second end forming a second end of the thermal blanket,
5 two edges forming respective edges of the thermal blanket, and an
6 undersurface forming an undersurface of the thermal blanket;
7 the first end, the second end, and respective edges of the base sheet
8 forming a periphery of the thermal blanket;
9 the base sheet including a first layer of flexible material and a
10 second layer of plastic material co-extensive with, and laminated to, the
11 first layer of flexible material;
12 an overlying flexible material sheet attached to the layer of plastic
13 material by a plurality of seals to form the base sheet and the overlying
14 sheet into an inflatable covering [which has a plurality of interconnected
15 inflatable chambers];

16 a seal between the overlaying material sheet and the base sheet
17 around the periphery;
18 said inflatable [chambers in said] covering for substantially
19 longitudinal disposition over a portion of said [a] patient's body extending
20 substantially from the pelvic area of said patient's body to the feet of said
21 patient's body;
22 an inflating inlet for admitting thermally controlled air into the
23 inflatable [chambers to inflate the] covering;
24 a plurality of apertures opening through the base sheet into the
25 inflatable covering [chambers] for exhausting thermally controlled air from
26 the [inflatable chambers through the base sheet in response to inflation and
27 erection of the] inflatable covering; and
28 [a seal between the overlaying material sheet and the base sheet
29 around the periphery]
30 a non-inflatable foot extension formed in the inflatable covering at
31 the second end for covering and warming said patient's feet.

1 27. (Amended) The inflatable thermal blanket of Claim 26, wherein said
2 thermal blanket is self-erecting [further including a non-inflatable foot extension formed
3 in the inflatable covering at the second end for enclosing and warming a patient's feet in
4 response to inflation of the inflatable covering].

1 28. (Amended) The inflatable thermal blanket of Claim 26 [27], wherein the
2 non-inflatable foot extension comprises the non-inflatable extension of the inflatable
3 covering beyond the second end.

1 29. (Amended) The inflatable thermal blanket of Claim 26 [27], wherein the
2 non-inflatable foot extension includes an extension of the base sheet beyond the second
3 end.

1 30. (Amended) The inflatable thermal blanket of Claim 26 [27], wherein the
2 plurality of seals are discontinuous elongate seams formed between the overlaying material
3 sheet and the sheet of plastic material.

1 31. (Amended) The inflatable thermal blanket of Claim 30, wherein the
2 discontinuous elongate seams form the overlaying material sheet into a [the] plurality of
3 inflatable chambers, the plurality of inflatable chambers including parallel, communicating
4 tubular chambers.

1 32. (Amended) The thermal blanket of Claim 30, wherein the non-inflatable
2 foot extension includes an extension of the base sheet beyond the second end.

1 33. (Amended) A thermal care system including the inflatable thermal
2 blanket of Claim 26 [27], and further including:
3 a heater/blower assembly for providing a source of heated air; and
4 a connecting hose coupled to the heater/blower assembly and to the inflating inlet
5 for conducting heated air from the heater/blower assembly into the inflatable covering.

1 34. (Amended) A method of warming a patient [person] using a thermal
2 blanket including an inflatable space formed between a flexible base sheet and an
3 overlaying material sheet attached to the base sheet by a peripheral seal around the
4 periphery of the thermal blanket and a plurality of seals inside the periphery of the
5 thermal blanket [that form the base sheet and overlaying material sheet into an inflatable
6 covering with a plurality of interconnected inflatable chambers], a non-inflatable section
7 formed in a portion of the inflatable thermal blanket, and apertures that open into the
8 inflatable space through the flexible base sheet for exhausting air from the inflatable
9 space, the method comprising the steps of:

10 disposing the thermal blanket to substantially longitudinally dispose the
11 inflatable space [chambers] over a portion of a patient's body extending
12 substantially from the pelvic area of said patient's body to the feet of said patient's
13 body, with the non-inflatable section disposed over the patient's feet;
14 inflating the thermal blanket with warmed air; [and]
15 exhausting warmed air through the apertures in the flexible sheet; and
16 using the non-inflatable section, retaining heat under the thermal blanket
17 near the patient's feet.

1 35. (Amended) The method of Claim 34, wherein the thermal blanket
2 [further includes a non-inflatable section formed in a portion of the periphery of the is
3 a self-erecting thermal blanket, the method further comprising the step[s] of:
4 [the non-inflatable section forming a non-inflatable foot drape in the thermal
5 blanket during the inflating step; and
6 using the non-inflatable foot drape, trapping and retaining the heat under the
7 thermal blanket during the exhausting step]
8 the inflatable thermal blanket self-erecting in the step of inflating.

REMARKS

Claims 26-31 and 33-35 have been amended. Claims 26-35 remain in the application.

A Petition for Extension of Time for Three Months accompanies this paper, together with a check to cover the requested extension.

A Terminal Disclaimer over U.S. Patent No. 5,184,612 is forwarded herewith, together with a check to cover the required terminal disclaimer fee.

An Information Disclosure Statement with the required fee also accompanies this paper.

The Examiner has rejected Claims 26-33 for obviousness-type double patenting over Claims 1-20 of U.S. Patent No. 5,184, 612. The Terminal Disclaimer accompanying this paper obviates the basis for this rejection and the Examiner is respectfully requested to remove it.

The Examiner has rejected Claim 34 for being anticipated by Augustine '188. Claim 34 has been amended to incorporate limitations respecting a non-inflatable extension for covering the feet. The Augustine '188 patent includes no such element and therefore does not anticipate Claim 34 as amended. Therefore, the Examiner is respectfully requested to withdraw this rejection.

In view of the amendments and remarks made in this paper and further in view of the Terminal Disclaimer accompanying this paper, it is submitted that all claims in this application are allowable over the prior art that is of record in this application.

Respectfully submitted,



Terrance A. Meador
Attorney for Applicant(s)
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

Telephone: (619) 233-9004

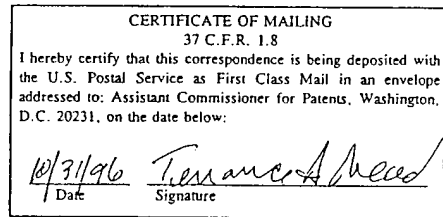
"PATENT"

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In re Application of:)	
S.D. AUGUSTINE, ET AL.)	Group Art Unit: 3304
Serial No.: 08/419,719)	
Filed: April 10, 1995)	Examiner: M. Graham
For: <u>INFLATABLE LOWER BODY</u>)	
THERMAL BLANKET (As Amended))	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:



PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(c)

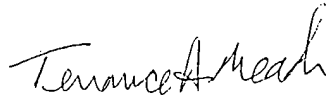
Applicant hereby petitions for a three month Extension of Time to respond to the Office Action mailed May 2, 1996, thereby extending the time to respond from August 2, 1996 to and including November 2, 1996.

Transmitted herewith is a Amendment and Request for Reconsideration in response to the Office Action.

Also transmitted herewith are a Terminal Disclaimer and an Information Disclosure Statement, PTO Form 1449 and the cited references.

A check in the amount of \$465 is enclosed herewith to cover the applicable fee for a three month extension of time as set forth in 37 CFR 1.17(c). Please charge any deficit or credit any excess to our Deposit Account No. 02-0460. Two copies of this letter are enclosed.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Terrance A. Meador". The signature is fluid and cursive, with the first name "Terrance" and last name "Meador" clearly distinguishable.

Terrance A. Meador
Attorney for Applicant(s)
Registration No. 30,298

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Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

Telephone: (619) 233-9004

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THERMAL BLANKET (As Amended))

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

CERTIFICATE OF MAILING	
37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below:	
10/31/96 Date	<i>T. Lawrence A. Mead</i> Signature

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(c)

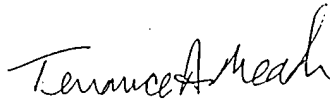
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10/31/96 Date	<i>Terrence A. Mead</i> Signature

INFORMATION DISCLOSURE STATEMENT

Applicant hereby cites the prior art listed in accompanying Form PTO-1449 with respect to the above-referenced patent application under the provisions of 37 C.F.R., Sections 1.56, 1.97 and 1.98. Copies of the documents are attached.

The filing of this Information Disclosure Statement will not be construed to mean that a search was conducted or that no other material information, as defined by 37 C.F.R. 1.56, exists.

Submitted herewith are a Deposition of Randall C. Arnold, a co-inventor in this application, and 4 of 5 exhibits that are cited in the Deposition.


The Examiner is urged to consider the entire deposition; however, the applicants respectfully draw the Examiner's attention to Pages 31 and 32, where reference is made to the annual meeting of the American Society of Anesthesiologists that was held in New Orleans in September, 1989.

Reference is also made to pages 37-40 where Exhibits 1,2, and 3 are explained and a "lower body OR surgical blanket" is mentioned.

Reference is also made to pages 101-104 where certain features of the lower body OR surgical blanket are discussed.

The Examiner is respectfully requested to make the listed documents of record in connection with the prosecution of the subjection application.

Respectfully submitted,



Terrance A. Meador
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Registration No. 30,298

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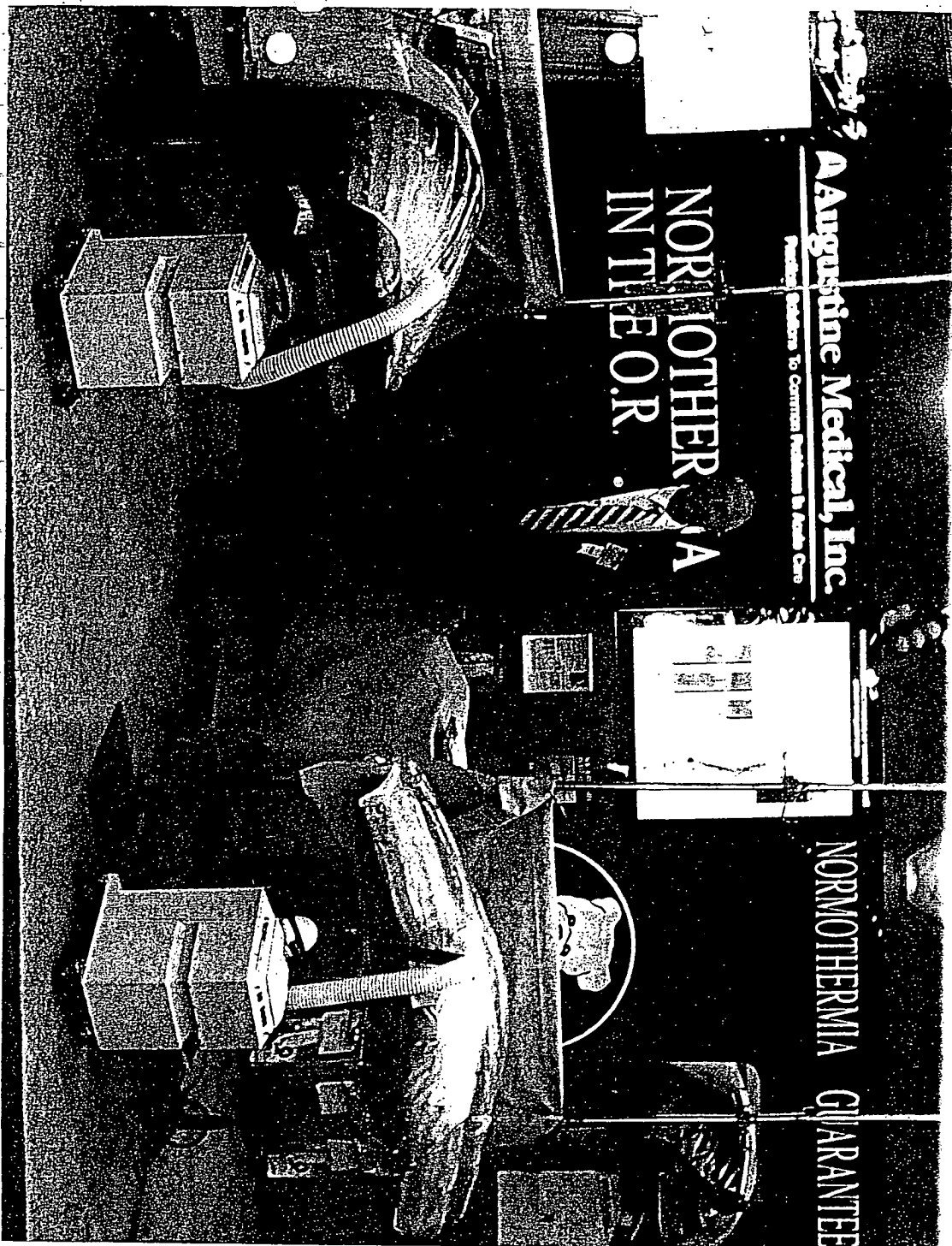
Telephone: (619) 233-9004

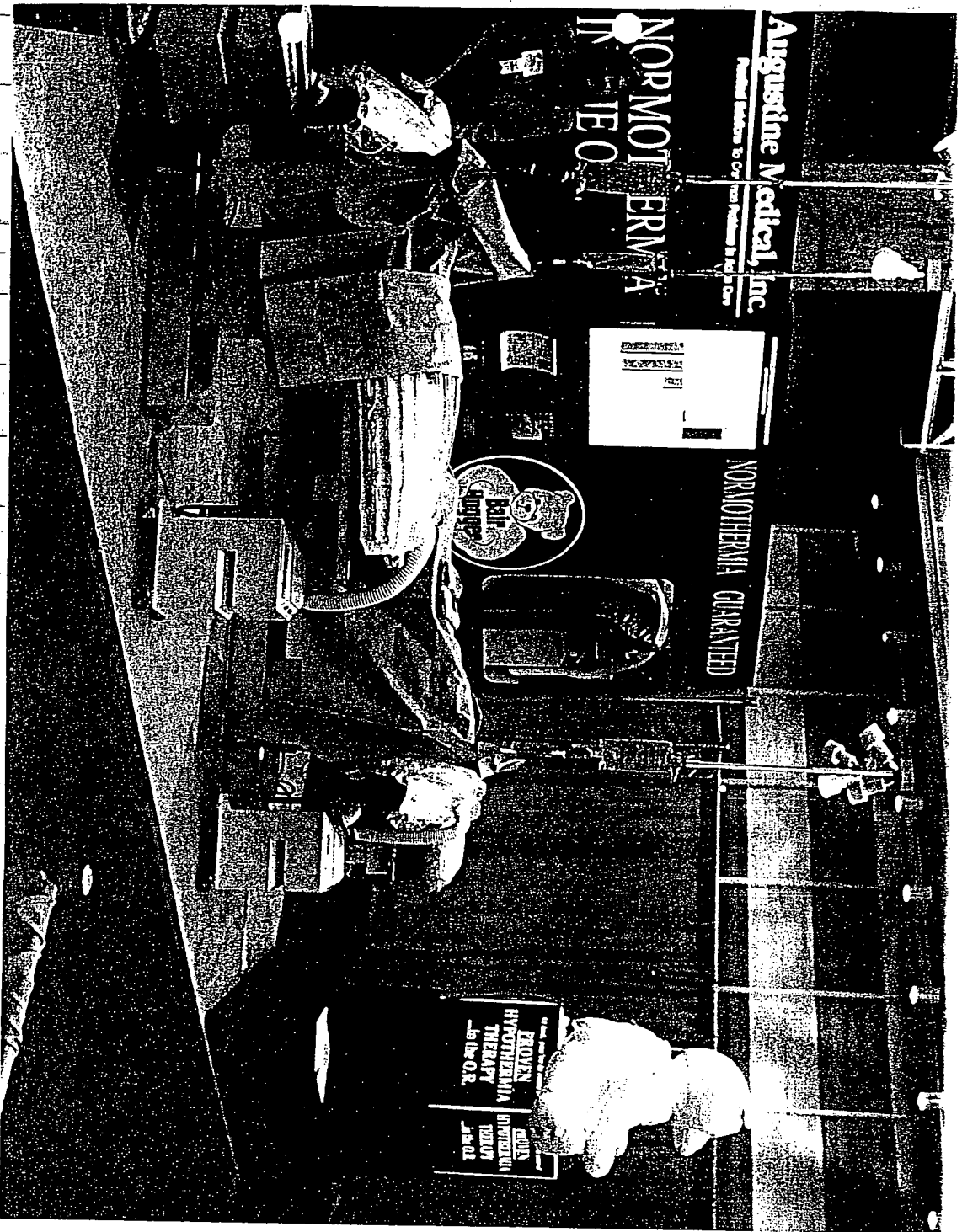
A Augustine Medical, Inc.

Proven Solutions To Critical Problems In Acute Care

**NORMOTHERMIA
IN THE O.R.**

**NORMOTHERMIA
GUARANTEE**





OTHERS GUARANTEED

100

Augustine Medical, Inc.
 Medical Devices To Control Problems In Adult Care

NORMOTHERMIA IN THE O.R.

At last, you're in control!
PROVEN
HYPOTHERMIA
THERAPY
...in the O.R.

At last, you're in control.

PROVEN
HYPOTHERMIA
THERAPY!
...in the O.R.

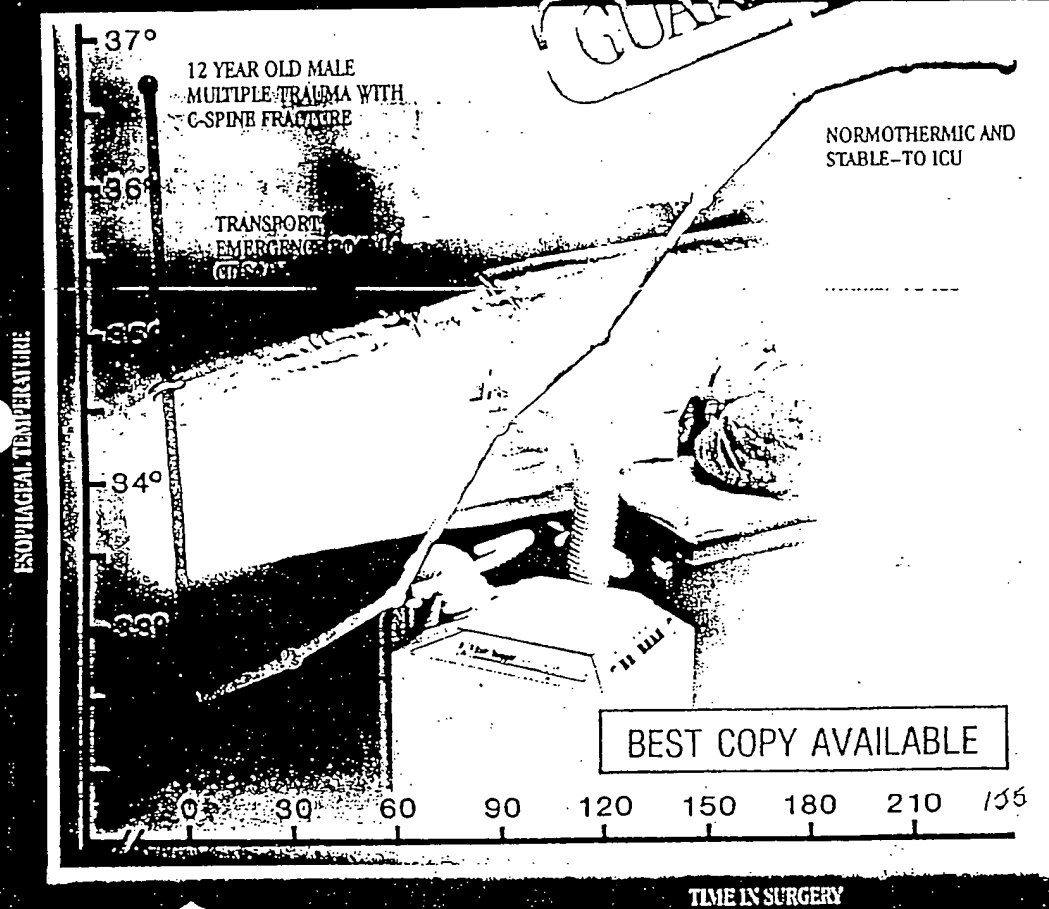
THE RMA GUARANTEE

JARAN EET

AUGUSTINE MEDICAL INTRODUCES...

NORMOTHERMIA IN THE O.R.

GUARANTEED



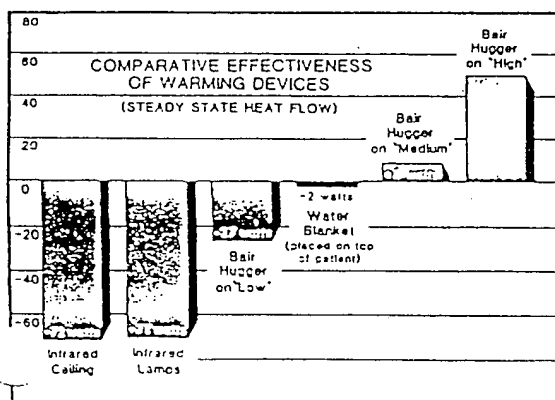
**BAIR HUGGER™
CONVECTIVE WARMING
THERAPY™ STARTED IN O.R.**

AT LAST, YOU'RE IN CONTROL!

Augustine Medical *guarantees* that Bair Hugger™ Convective Warming Therapy™ will maintain normothermia in the O.R. Far too often patients become seriously hypothermic despite the physician's best efforts. In fact, studies show that 60%-80% of all O.R. patients are hypothermic when treated with the traditional "warming" devices,¹ which are virtually ineffective.² Bair Hugger Convective Warming Therapy™ has *actively* warmed over 150,000 hypothermic PACU patients in its first year of use. Its effectiveness has been documented in several clinical studies.^{3,4} The proven effectiveness of Bair Hugger Therapy establishes a new standard of care. With Bair Hugger Convective Warming Therapy, hypothermia in the O.R. is a problem of the past, *guaranteed!*⁵

Bair Hugger™ Convective Warming Therapy™ is the Only Proven Method of Active Surface Warming.

All of the available methods of surface warming were tested for effectiveness at the University of California-San Francisco. Using heat flux transducers in a controlled laboratory setting, Dr. Dan Sessler found that only Bair Hugger Therapy actively transfers heat to the patient. "... (Bair Hugger Therapy) provided enough heat to increase body temperature almost 3°C per hour.⁶" The other technologies did not transfer heat to the patient and in fact could not even prevent the patients from losing their endogenous heat.⁷



"The Bair Hugger™ is the first device that allows you to choose your patient's temperature and keep them there. We've had control of blood pressure and pulse for years, now we can finally control temperature."

Neil Feinglass, M.D., Jacksonville, FL

"Bair Hugger Body Heat"

— American Anesthesiologist



Bair Hugger



Loss of

of
press release,
Orleans, LA, 1989

"The injured patient arrived in the O.R. cold and bradycardic. Active warming with the Bair Hugger™ resulted in a rapid improvement of the temperature and stabilization of the heart rate."

—K.G. Belani, M.D., Minneapolis, MN

CONVECTIVE WARMING THERAPY™



Bair Hugger™ Warming Covers are Available in Two Styles

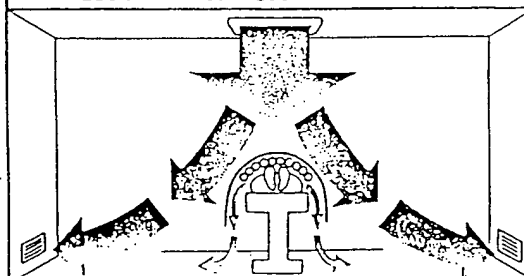
A chest/arm Cover for abdominal and lower extremity operations and a leg Cover for abdominal, thoracic and intracranial operations.

Localized Air Flow

The combination of the Steridrape™ (3M, St. Paul, MN) barrier design and the overlying surgical drape, prevents the warm exhaust air from migrating toward the surgical incision. The heated air flows from under the surgical drape toward the floor. It is then carried directly toward the room exhaust vents by the large volume of room ventilation air which is blowing directly down on the patient from the ceiling.

The warm air contributes less than 3% of the total air circulation in the O.R. and is undetectable at the surgical site. Bair Hugger air is filtered through a 0.2 micron filter before heating.

O.R. AIRFLOW IN THE OPERATING ROOM
AIRFLOW: 1,300 - 26,000 CU.FT./MINUTE
VELOCITY: 20 - 200 LIN.FT./MINUTE



BAIR HUGGER™ AIRFLOW: 35 CU.FT./MINUTE
VELOCITY: 3 LIN.FT./MINUTE
(0.1-2% OF TOTAL AIRFLOW DIRECTED AWAY FROM THE INCISION)



Bair Hugger™ Convective Warming Therapy is:

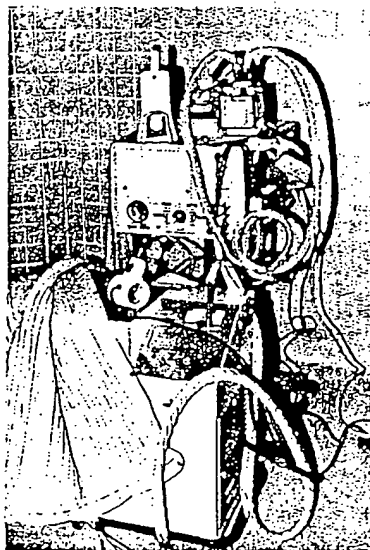
Safe Convective Warming is as safe as warming up the room temperature. In contrast, water based warming technologies such as water mattresses and heated humidifiers have caused numerous cases of full thickness burns and tracheal damage.⁽¹⁾

Convenient The Bair Hugger Warming System can also warm I.V. fluids and blood! Up to one liter/hour of room temperature fluid can be warmed by simply adding two lengths of extension tubing to the I.V. line and placing them between the warm air tubes of the Cover.

Up to three liters/hour of cold blood can be warmed with a Bair Hugger™ Fluid Warming Cassette which is inserted into the center air tube. Traditional fluid warmers allow the fluid to cool during the six foot transit to the patient. The Bair Hugger System keeps the fluid warm right up to the I.V. site. Bair Hugger fluid warming is inexpensive, efficient and reduces equipment needs.

Cost Effective Our simple and safe warming therapy eliminates any need for water mattresses and airway heaters. For humidification of the tracheal mucosa, we do recommend the use of an "artificial nose" (airway Heat and Moisture Exchanger). The Bair Hugger fluid warming capability makes blood/fluid warmers unnecessary in all but the very large volume resuscitations.

Practical Bair Hugger Convective Warming Therapy consists of a Heating Unit and a disposable Warming Cover that directs a gentle flow of warm air across the patient's body which provides for



Bair Hugger™ Therapy allows you the freedom to concentrate on the patient, not on the equipment!

safe and effective warming. The Bair Hugger Heating Unit uses a reliable, High efficiency blower, a sealed 850 Watt heating element, and a microprocessor based temperature controller to create a continuous flow of warm air. The patented Warming Cover is made of a layer of plastic and a layer of tissue paper/plastic laminate, bonded together into long tubular channels. When inflated, the self-supporting Warming Cover is designed to arch over the patient's body, creating a warm "cocoon". The warm air exits through microperforations in the Cover's underlayer, resulting in convective warming as it surrounds the patient.

Free Trial If you are interested in effective, safe and convenient patient warming, a free trial of Bair Hugger Convective Warming Therapy can quickly be arranged. Just call us toll free at:

1-800-733-7775
or (612) 941-8866

***Terms of guarantee:**

1. Bair Hugger™ Convective Warming Therapy™ must begin immediately after induction of anesthesia on the "high" setting and continue throughout the case if indicated.
2. Infused blood and fluids must be warmed to body temperature.

If these two criteria are met and the patient is hypothermic at the end of the operation (core temperature 36°C), Augustine Medical will replace the Warming Cover. This guarantee is limited to the replacement of the Warming Cover.

SPECIFICATIONS HEAT/BLOWER UNIT

Size:	23" high x 16" deep x 14" wide
Weight:	32 lbs
Power Requirements:	110 VAC
Temperature Range:	Ambient to 110°F Max
Enclosure:	Enamelled Steel
Power Cable:	14 Feet Long
Filter:	High efficiency 0.2 air filter
Covers	
Arm Cover Size:	82" x 20"
Leg Cover Size:	32" x 36"
Weight:	6 ounces
Material:	Polyethylene and tissue paper laminate.



AUGUSTINE MEDICAL INC.

PRACTICAL SOLUTIONS TO COMMON PROBLEMS IN ACUTE CARE™

10393 West 70th Street • Eden Prairie, Minnesota 55344
Phone: 1-800-733-7775

BEST COPY AVAILABLE

(1) Vaughn MH, et al: Anesth Analg 50:746-751, 1981. (2) Sessler D, et al: Oral Presentation American Society of Anesthesiologists Annual Meeting, New Orleans, LA 1989 (In Press). (3) Morris PR, et al: Anesthesiology 36:408-411, 1972. (4) Code ML, et al: Aviation, Space & Environ Med 48:525-532, 1977. (5) Sessler D, et al: Anesthesiology 71:A110, 1989. (6) Conover MA, et al: A&A 68:539, 1989. (7) Cristobal SB, et al: Poster presentation, AORN National Congress, Anaheim CA, Feb. 1989. (8) Sessler D, et al: In press 1989. (9) Bair Hugger™ Prevents Loss of Body Heat: American Society of Anesthesiologists, Press release, ASA Annual Meeting, New Orleans, LA, Oct 1989. (10) Scott AM: Arch Surg 94:181, 1962. (11) Crino MH, et al: Anesthesiology 29:149-150, 1966. (12) Sims NM, et al: Anesthesiology 65:A490, 1986. (13) Klein EF, et al: Chest 55:225-226, 1974. (14) Stoenen WS: Medical Instrumentation 16:53-56, 1982. For a complete bibliography, call 1-800-733-7775.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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S.D. Augustine et al) Group No.: 3304
Serial No.: 08/419,719)
Filed: April 10, 1995) Examiner: M. Graham
For: THERMAL BLANKET)

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Dear Sir:

TERMINAL DISCLAIMER

Your Petitioner, AUGUSTINE MEDICAL, INC., represents that:
by virtue of an Assignment recorded in the United States
Patent Office on 6/25/92, at Reel 6147, Frame 0720, it is the
owner of the entire right and interest in United States Patent
5,184,612, which issued February 9, 1993;

by virtue of an Assignment recorded in the United States
Patent Office on 2/23/90 at Reel 5244, Frame 0712 it is the
owner of the entire right and interest in United States Patent
Application Serial No. 07/227,189 (abandoned);

by virtue of an Assignment recorded in the United States Patent Office on 8/31/90 at Reel 5427, Frame 0875, it is the owner of the entire right and interest in United States Patent Application No. 07/550,757 (a continuation-in-part of United States Serial No. 07/227,189, and now abandoned); and


by virtue of an Assignment recorded in the United States Patent Office on 4/13/92 at Reel 6082, Frame 0560, it is the owner of the entire right and interest in United States Patent Application Serial No. 07/638,748 (a continuation-in-part of United States Serial No. 07/550,757, and now United States Patent No. 5,405,371), and thereby the owner of the entire right and interest in this patent application, United States Patent Application Serial No. 08/419,719 (a continuation of United States Serial No. 07/638,748).

Your petitioner, AUGUSTINE MEDICAL, INC., hereby disclaims the terminal part of any patent granted on United States Patent Application Serial No. 08/419,719 which would extend beyond the expiration date of United States Patent 5,184,612 and hereby agrees that any patent so granted on United States Patent Application Serial No. 08/419,719 shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to United States Patent 5,184,612, this agreement to run with any patent granted on United States Patent Application Serial No. 08/419,719 and to be binding upon the grantee, its successors or assigns.

I have reviewed the evidentiary documents concerning ownership of United States Patent 5,184,612 and United Application Serial No. 08/419,719 and, to the best of my knowledge and belief, they establish the entire right, title, and interest to United States Patent 5,184,612 and to United States Patent Application Serial No. 08/419,719 in AUGUSTINE MEDICAL, INC.

I, JOHN E. THOMAS, am President of AUGUSTINE MEDICAL, INC., and I am authorized to sign this Terminal Disclaimer on behalf of AUGUSTINE MEDICAL, INC.

Dated: 5/22/96


JOHN E. THOMAS, President
AUGUSTINE MEDICAL, INC.



ASSISTANT SECRETARY OF COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

TO: TERRANCE A. MEADOR
BAKER, MAXHAM, JESTER & MEADOR
SUITE 1202
110 WEST "C" STREET
SAN DIEGO, CA 92101

RECEIVED

MAY 03 1990

Baker, Maxham, Jester & Meador

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE U.S. PATENT AND TRADEMARK OFFICE ON THE REEL AND FRAME NUMBER REFERENCED BELOW. A DIGEST OF THE DOCUMENT HAS ALSO BEEN MADE AND APPEARS IN THE OFFICE'S RECORDS AS SHOWN:

ASSIGNOR: 001 AUGUSTINE, SCOTT D.
ASSIGNOR: 002 AUGUSTINE, DOUGLAS J.

DOC DATE: 02/07/90
DOC DATE: 02/07/90

RECORDATION DATE: 02/23/90 NUMBER OF PAGES 001 REEL/FRAME 5244/0712

DIGEST: ASSIGNMENT OF ASSIGNORS INTEREST

ASSIGNEE: 501 AUGUSTINE MEDICAL, INC., 10393 WEST 70TH STREET, SUITE 100, EDEN PRAIRIE, MN A CORP. OF MN

SERIAL NUMBER 7-227189 FILING DATE 08/02/88
PATENT NUMBER _ ISSUE DATE 00/00/00

TITLE OF INVENTION: THERMAL BLANKET

- INVENTOR: 001 AUGUSTINE, SCOTT D.
INVENTOR: 002 AUGUSTINE, DOUGLAS J.

ASSIGNMENT

WHEREAS, SCOTT D. AUGUSTINE, 9017 Cavell Circle, Bloomington, Minnesota, 55438, and DOUGLAS J. AUGUSTINE, 18546 Avon Court, Eden Prairie, Minnesota, 55346, hereinafter referred to as Assignors have acquired rights to a certain invention and a United States patent application covering the same; and

WHEREAS, in accordance with the terms of an agreement dated 7/15/87, the Assignors have agreed with AUGUSTINE MEDICAL, INC., a corporation of the State of Minnesota, having a principal place of business at 10393 West 70th Street, Suite 100, Eden Prairie, Minnesota, 55344, hereinafter referred to as the Assignee, the Assignors have agreed to assign these rights to the Assignee; and

NOW, THEREFORE, be it known that for good and valuable consideration, the Assignors do hereby formally grant, bargain, sell, transfer, convey and assign to the Assignee, its successors, legal representatives or assigns, the entire right, title, and interest in and to United States Patent Application Serial No. 07/227,189, filed August 2, 1988 and entitled "THERMAL BLANKET", and all continuations and divisions thereof, said U.S. Patent Application to be held and enjoyed by the Assignee for its own use and enjoyment and for the use and enjoyment of its successors, assigns or other legal representatives as fully and entirely as the same would have been held and enjoyed by the Assignors had this Assignment not been made.

The Assignors covenant that they have the right to grant this Assignment.

Executed at Eden Prairie, Minnesota, this 7th day of February, 1990.

Scott D. Augustine
SCOTT D. AUGUSTINE

Douglas J. Augustine
DOUGLAS J. AUGUSTINE

Witness: Terance A. Meado

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Maxham, Jester & Meador



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

TERRANCE A. MEADOR
BAKER, MAXHAM, JESTER & MEADOR
110 WEST "C" ST., STE. 1202
SAN DIEGO, CA 92101

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NUMBER REFERENCED BELOW. A DIGEST OF THE DOCUMENT HAS ALSO BEEN MADE
AND APPEARS IN THE OFFICE'S RECORDS AS SHOWN:

SIGNOR: 001 AUGUSTINE, SCOTT D.
SIGNOR: 002 ARNOLD, RANDALL C.

DOC DATE: 08/21/90
DOC DATE: 08/22/90

RECORDATION DATE: 08/31/90 : NUMBER OF PAGES 003 REEL/FRAME 5427/0875

TEST: ASSIGNMENT OF ASSIGNORS INTEREST

SIGNEE: 501 AUGUSTINE MEDICAL, INC., 10393 WEST 70TH ST., STE. 100, E
MINNAPRAIRIE, MN 55344

SERIAL NUMBER 7-550757 FILING DATE 07/10/90
PATENT NUMBER ISSUE DATE 00/00/00



LING E. BAKER
RENCE A. MAXHAM
HAEL H. JESTER
RANCE A. MEADOR
TER W. DUFT

BAKER, MAXHAM, JESTER & MEADOR
A PROFESSIONAL CORPORATION
ATTORNEYS AT LAW
SUITE 1202
110 WEST "C" STREET
SAN DIEGO, CALIFORNIA 92101
(619) 233-9004
FACSIMILE (619) 544-1246

PATENTS
TRADEMARKS
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NORTH COUNTY OFFICE
2111 PALOMAR AIRPORT ROAD
SUITE 330
CARLSBAD, CA 92009
(619) 438-3007

August 28, 1990

Hon. Commissioner of Patents and Trademarks
Washington, D. C. 20231

Dear Sir:

Enclosed please find an Assignment from SCOTT D. AUGUSTINE,
and RANDALL C. ARNOLD to AUGUSTINE MEDICAL, INC., for U.S.
Patent Application Serial No. 07/550,757, filed July 10, 1990,
for "THERMAL BLANKET".

Kindly record the enclosed Document and return it to the
undersigned.

Our check in the amount of \$8.00 is enclosed for the recordal
fee. If any additional fees arise in connection with this
recording which are not covered by the money enclosed, please
charge such fees, or credit any overpayment, to Deposit
Account No. 02-0460. A duplicate copy of this letter is
enclosed.

Very truly yours,

BAKER, MAXHAM, JESTER & MEADOR

Terrance A. Meador

TERRANCE A. MEADOR
Registration No. #30,298

TAM/cmr
Enclosures

RECEIVED
90 SEP 12 AM 7:58
ASSIGNMENT BRANCH

11154271RME875

91124708

ASSIGNMENT

TO WHOM IT MAY CONCERN

For valuable consideration, be it known that we, SCOTT D. AUGUSTINE, 9017 Cavell Circle, Bloomington, Minnesota, 55438, and RANDALL C. ARNOLD, 1701 Payne Avenue, Maplewood, Minnesota, 55117, have sold, assigned and transferred and by these presents do sell, assign, transfer and set over unto AUGUSTINE MEDICAL, INC., 10393 West 70th Street, Suite 100, Eden Prairie, Minnesota, 55344, its successors, legal representatives, or assigns, our whole right, title and interest, in and to a certain invention relating to "THERMAL BLANKET" and United States Patent Application therefor, Serial No. 07/550,757, filed in the United States Patent and Trademark Office on July 10, 1990, and all original and reissue patents granted thereof, and all divisions and continuations thereof, including the subject matter of any and all claims in every such patent, and all foreign rights to said invention, and covenant that we have full right to do so, and agree that we will communicate to said AUGUSTINE MEDICAL, IN., or its representatives all facts known to us respecting said invention, whenever requested, and testify in any legal

FILED 54 27 11 AM '87 6

proceedings, sign all lawful papers, make all rightful oaths and generally do everything possible to aid said AUGUSTINE MEDICAL, INC., its successors, assigns, and nominees, to obtain and enforce proper patent protection for said invention in the United States of America and throughout the World.

The Commissioner of Patents and Trademarks is requested to issue the Letters Patent which may be granted for said invention or any part thereof unto said AUGUSTINE MEDICAL, INC., in keeping with this Assignment.

Dated: 8/21/90

Scott D. Augustine
SCOTT D. AUGUSTINE

Dated: 8/22/90

Randall C. Arnold
RANDALL C. ARNOLD

Dated: 8-22-90

Kathleen White
WITNESS

RECORDED
PATENT AND TRADEMARK
OFFICE

AUG 31 1990

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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JUN 01 1992

Baker, Maxham, Jester & Meador

DATE: 05/11/92
TO:
TERRANCE A. MEADOR
BAKER, MAXHAM, JESTER & MEADOR
750 B STREET, SE. 2770
SAN DIEGO, CA 92101

UNITED STATES PATENT AND TRADEMARK OFFICE
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PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT ASSIGNMENT PROCESSING SYSTEM. IF YOU SHOULD FIND ANY ERRORS, ON THIS NOTICE, PLEASE SEND A REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT BRANCH, NORTH TOWER BUILDING, SUITE 10C35, WASHINGTON, D.C. 20231

ASSIGNOR:
AUGUSTINE, SCOTT D.

DOC DATE: 01/07/91

ASSIGNOR:
ARNOLD, RANDALL C.

DOC DATE: 01/07/91

RECORDATION DATE: 04/13/92 NUMBER OF PAGES 003 REEL/FRAME 6082/0560

LEGEST :ASSIGNMENT OF ASSIGNORS INTEREST

ASSIGNEE:
AUGUSTINE MEDICAL, INC.
10393 WEST 70TH STREET, STE. 100, EDEN PRAIRIE, MN 55344

SERIAL NUMBER 7-638748 FILING DATE 01/08/91
PATENT NUMBER ISSUE DATE 00/00/00

17

RELING E. BAKER
LAWRENCE A. MAXHAM
MICHAEL H. JESTER
TERRANCE A. MEADOR
ALTER W. DUFT
TIMES A. WARD

BAKER, MAXHAM, JESTER & MEADOR

A PROFESSIONAL LAW CORPORATION

SYMPHONY TOWERS
750 'B' STREET, SUITE 2770
SAN DIEGO, CALIFORNIA 92101
TEL. (619) 231-8004
FACSIMILE (619) 344-1246

PATENTS
TRADEMARKS
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April 10, 1992

Hon. Commissioner of Patents and Trademarks
Washington, D. C. 20231

Re: Assignment Recordal Request for
U.S. Patent Application for
"THERMAL BLANKET"
Our Ref.: 1342 35

Dear Sir:

Enclosed please find an Assignment from SCOTT D. AUGUSTINE and RANDALL C. ARNOLD, to AUGUSTINE MEDICAL, INC., for U.S. Patent Application Serial No. 07/638,748, filed January 8, 1991, for "THERMAL BLANKET".

Kindly record the enclosed Document and return it to the undersigned.

Our check in the amount of \$40.00 is enclosed for the recordal fee. If any additional fees arise in connection with this recording which are not covered by the money enclosed, please charge such fees, or credit any overpayment, to Deposit Account No. 02-0460. A duplicate copy of this letter is enclosed.

Very truly yours,

BAKER, MAXHAM, JESTER & MEADOR

TERRANCE A. MEADOR
Registration No. #30,298

TAM/cmr
Enclosures

050 LP 04/17/92 07638748

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APR 24 AM 10:01
PATENT & TRADEMARK OFFICE

ASSIGNMENT

TO WHOM IT MAY CONCERN

For valuable consideration, be it known that we, SCOTT D. AUGUSTINE, 9017 Cavell Circle, Bloomington, Minnesota, 55438, and RANDALL C. ARNOLD, 1701 Payne Avenue, Maplewood, Minnesota, 55117, have sold, assigned and transferred and by these presents do sell, assign, transfer and set over unto AUGUSTINE MEDICAL, INC., 10393 West 70th Street, Suite 100, Eden Prairie, Minnesota, 55344, its successors, legal representatives, or assigns, our whole right, title and interest, in and to a certain invention relating to "THERMAL BLANKET" and United States Patent Application therefor, executed on even date herewith, and all original and reissue patents granted thereof, and all divisions and continuations thereof, including the subject matter of any and all claims in every such patent, and all foreign rights to said invention, and covenant that we have full right to do so, and agree that we will communicate to said AUGUSTINE MEDICAL, INC., or its representatives all facts known to us respecting said invention, whenever requested, and testify in any legal

11/16/82 11:11:56

proceedings, sign all lawful papers, make all rightful oaths and generally do everything possible to aid said AUGUSTINE MEDICAL, INC., its successors, assigns, and nominees, to obtain and enforce proper patent protection for said invention in the United States of America and throughout the World.

The Commissioner of Patents and Trademarks is requested to issue the Letters Patent which may be granted for said invention or any part thereof unto said AUGUSTINE MEDICAL, INC., in keeping with this Assignment.

Dated: 1/7/91

Scott D. Augustine
SCOTT D. AUGUSTINE

Dated: 1/7/91

Randall C. Arnold
RANDALL C. ARNOLD

Dated: 7 Jan 91

James W. Gordon
WITNESS

RECORDED
PATENT AND TRADEMARK
OFFICE

APR 13 1992

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RECEIVED

MAY 06 1996

Baker, Maxham, Jester & Meador



1342-119
UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/412-713	05/10/95	AUGUSTINE	1342-119
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TERENCE A. MEADOR
BAKER MAXHAM JESTER & MEADOR
SYMPHONY SQUARE
1100 R STREET SUITE 2770
SAN DIEGO CA 92101

PSM1/0502

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

DATE MAILED:

05-02-96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

MAY 06 1996

DOCKETED

Office Action Summary	Application No. 08/419,719	Applicant(s) Augustine et al.
	Examiner Mark S. Graham	Group Art Unit 3304

☒ Responsive to communication(s) filed on 7/10/95, 10/12/95

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 26-35 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 26-34 is/are rejected.

☒ Claim(s) 35 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 3304

Claims 26-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,184,612. Although the conflicting claims are not identical, they are not patentably distinct from each other because removal of the additionally claimed elements with their corresponding loss of function would have been obvious to one of ordinary skill in the art.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 34 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Augustine '188.

Claim 35 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Serial Number: 08/419,719

-3-

Art Unit: 3304

Any inquiry concerning this communication should be directed to Mark S. Graham at telephone number (703) 308-1355.

MSG
April 26, 1996

MARK S. GRAHAM
PRIMARY EXAMINER
GROUP 3300

PTO-1449
Rev. 7-80

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

SERIAL NO.

Sheet 1 of 1

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(Use several sheets if necessary)

0545PA-09-1842-119

07/227,189

APPLICANT

SCOTT D. AUGUSTINE, ET AL

FILING DATE

August 2, 1988

GROUP

334

U.S. PATENT DOCUMENTS

AMINER TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AK	AA	2 2 2 6 9 0	Dec. 16, 1879	S. GOLDSCHMIDT	128	403	07/21/1879
AK	AB	1 3 9 9 0 9 5	Dec. 6, 1921	J.F. WEBB, SR.	128	402	12/02/19
AK	AC	1 7 7 7 9 8 2	Oct. 7, 1930	K. POPP	128	399	06/10/29
AK	AD	2 0 9 3 8 3 4	Sept 21, 1937	R.S. GAUGLER	128	402	04/20/31
AK	AE	2 6 0 1 1 8 9	June 17, 1952	N.B. WALES, JR.	4	160	08/22/49
AK	AF	2 7 0 6 9 8 8	Apr. 26, 1955	H. WEBER	128	402	09/15/52

OTHER PRIOR ART (including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER

DATE CONSIDERED

4/1/89

The USPTO date stamp hereon will acknowledge receipt of:

STATUS INQUIRY for "Thermal Blanket"

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995
Mailed: March 15, 1996

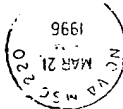
TAM/cmr
1342-119

USPTO date stamp hereon will acknowledge receipt of:

STATUS INQUIRY for "Thermal Blanket"

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995
Mailed: March 15, 1996

1342-119



"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
S.D. Augustine et al) Group No.: 3304
Serial No.: 08/419,719)
Filed: April 10, 1995) Examiner: M. Graham
For: THERMAL BLANKET)

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

CERTIFICATE OF FACSIMILE TRANSMISSION	
37 C.F.R. 1.8	
I hereby certify that this correspondence is being facsimile transmitted to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below:	
3/15/96	Terrance A. Meador
Date	Signature

Dear Sir:

STATUS INQUIRY

Applicants respectfully request that they be notified of the status of this application.

Respectfully submitted,

Terrance A. Meador

TERRANCE A. MEADOR
Attorney for Applicant(s)
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101
Telephone: (619) 233-9004

NOV 17 1995



Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Serial Number	Filing Date	First Named Applicant	Attorney Docket No.
08/11/95	08/11/95	COMMISSIONER	

RECEIVED & FORWARDED
TO THE PATENT AND TRADEMARKS
COMMISSIONER
U.S. DEPARTMENT OF COMMERCE
WASHINGTON, D.C. 20231

EXAMINER	
PERMANENT	
ART UNIT	PAPER NUMBER
	6

DATE MAILED:

Below is a communication from the EXAMINER in charge of this application
COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☐ THE PERIOD FOR RESPONSE:

- ☐ is extended to run _____ from the date of the Final Rejection
- ☐ continues to run _____ from the date of the Final Rejection
- ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date that the shortened statutory period for response expires as set forth above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☐ Applicant's response to the final rejection, filed _____, has been considered with the following affect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:

- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- b. ☐ They raise new issues that would require further consideration and/or search. (See Note).
- c. ☐ They raise the issue of new matter. (See Note).
- d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☐ Upon the filing of an appeal, the proposed amendment ☐ will be ☐ will not be, entered and the status of the claims in this application would be as follows:

Allowed claims: _____

Claims objected to: _____

Claims rejected: _____

However:

- a. ☐ The rejection of claims _____ on references is deemed to be overcome by applicant's response.
- b. ☐ The rejection of claims _____ on non-reference grounds only is deemed to be overcome by applicant's response.

4. ☐ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other

* New first action withdrawing finality of previous action will follow.

MARK S. GRAHAM
PRIMARY EXAMINER
GROUP 3300

***** -COMM. JOURNAL- ***** DATE OCT-12- 5 ***** TIME 15:43 ***** P.01

MODE = TRANSMISSION

START=OCT-12 15:39

END=OCT-12 15:43

NO.	COM	ABBR/NTWK	STATION NAME/ TELEPHONE NO.	PAGES
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***** (FAX-900 01.36)***** -

- ***** -

- *****

BAKER, MAXHAM, JESTER & MEADOR

LING E. BAKER
VRENCIA A. MAXHAM
JHAEL H. JESTER
RANCE A. MEADOR
LTER W. DUFT

A PROFESSIONAL LAW CORPORATION

SYMPHONY TOWERS
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AD A. HALL
EVIN PERKINS

OUNSEL
IN F. JOHNSTON
N C. LAMBERTSEN

~~CONFIDENTIAL~~

ATTORNEY/CLIENT PRIVILEGED COMMUNICATION

(Please Call (619) 233-9004 If Received In Error)

DATE: October 12, 1995

TO: Examiner M. Graham

COMPANY: United States Patent and Trademark Office

FAX NO.: 703/305-3590

FROM: T.A. Meador

RE: 08/419,719

Our Reference No.: 1342-119

NUMBER OF PAGES INCLUDING COVER SHEET: 11

If transmission is poor, or if you do not receive all pages, please call (619) 233-9004 as soon as possible.

COMMENTS: _____

"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
)
S.D. Augustine et al) Group No.: 3304
)
Serial No.: 08/419,719)
) Examiner: M. Graham
Filed: April 10, 1995)
)
For: THERMAL BLANKET)

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

CERTIFICATE OF FACSIMILE TRANSMISSION 37 C.F.R. 1.8	
I hereby certify that this correspondence is being facsimile transmitted to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below:	
<u>10/12/95</u> Date	<u>Tennison A. Read</u> Signature

Dear Sir:

REQUEST FOR RECONSIDERATION

In response to the Final Action dated September 14, 1995 in this application, the Examiner is respectfully requested to reconsider and withdraw the Final Action (Paper 3).

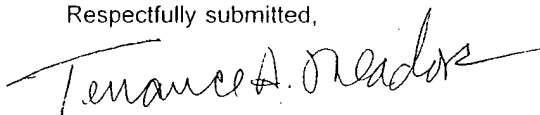
The applicant submitted a Preliminary Amendment by first class mail certificate dated July 7, 1995. The applicant received a postcard stamped by the Patent Office mail room acknowledging receipt of the Preliminary Amendment on July 10, 1995. Copies of the Preliminary Amendment and stamped receipt are enclosed.

By the Preliminary Amendment, the applicant confirmed cancellation of Claims 4-7 and 11-25 made in the transmittal of the application. The applicant further cancelled Claims 1-3 and 8-9. Claims 26-35 were added to the application.

The mailing date of the Final Action is September 14, 1995, more than two (2) months after receipt of the Preliminary Amendment by the Patent Office. Accordingly, the Preliminary Amendment, while having been received by the Patent Office, was manifestly not considered by the Examiner when the Final Action was prepared and issued.

Since the Preliminary Amendment was timely and preceded the Final Action, the Examiner is respectfully requested to reconsider and withdraw the Final Action and to issue an Official Action based on examination of the claims that are at issue in this application.

Respectfully submitted,

A handwritten signature in cursive script, reading "Terrance A. Meador".

TERRANCE A. MEADOR
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

Phone: 619/233-9004
Fax: 619/544-1246

The USPTO date stamp hereon will acknowledge receipt of:
PRELIMINARY AMENDMENT for "Thermal Blanket" (6 pages)

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995
Mailed: July 7, 1995
Enclosed: Copy of page 671 of Dictionary

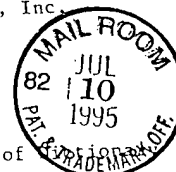
TAM/cmr
1342-119

The USPTO date stamp hereon will acknowledge receipt of:
PRELIMINARY AMENDMENT for "Thermal Blanket" (6 pages)

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995

Mailed: July 7, 1995

Enclosed: Copy of page 671 of Dictionary



RECEIVED

AUG 04 1995

TAM/cmr
1342-119

"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
SCOTT D. AUGUSTINE) Group No.: 3311
Serial No.: 08/419,719)
Filed: April 10, 1995) Examiner: Unknown
For: THERMAL BLANKET)

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below:	
7/7/95 Date	<i>Terrence A. Reed</i> Signature

Dear Sir:

PRELIMINARY AMENDMENT

Prior to the first examination, please amend the above-identified
patent application as follows:

IN THE ABSTRACT

Please cancel the recitation of the Abstract and substitute the
following therefor:

--A thermal blanket includes an inflatable covering
with a head end, a foot end, two edges, and an
undersurface. The covering includes a plurality of
inflatable chambers that are inflated when a thermal-

controlled inflating medium is introduced into the thermal blanket through an inlet at the foot end. When inflated, the thermal blanket self-erects into a structure and provides a bath of thermally-controlled inflating medium to the interior of the erected structure through an aperture array on the undersurface of the inflatable covering. The thermal blanket is constructed for substantially longitudinal disposition over a portion of a patient's body extending from the pelvic area to the feet of the patient's body. Provision may be made for securing the inflatable covering to the patient's body at the head end. Provision may further be made for an uninflatable foot drape at the foot end.--

IN THE DESCRIPTION

Page 9, line 26, please change "20" to --10--.

Page 20, line 2, please change "heater" to --connecting--;

line 3, please change each occurrence of "tube" to --hose--; and

line 18, please change "heater tube" to --connecting hose--.

IN THE CLAIMS

The cancellation of Claims 4-7 and 11-25 in the transmittal of this application on April 10, 1995 is confirmed. Please cancel Claims 1-3 and 8-9. Please add the following claims:

- 1 26. (Added) An inflatable thermal blanket for covering and
- 2 bathing a portion of a patient's body with thermally-controlled air,

comprising:

a flexible base sheet having a first end forming a first end of the thermal blanket, a second end forming a second end of the thermal blanket, two edges forming respective edges of the thermal blanket, and an undersurface forming an undersurface of the thermal blanket;

the first end, the second end, and respective edges of the base sheet forming a periphery of the thermal blanket;

the base sheet including a first layer of flexible material and a second layer of plastic material co-extensive with, and laminated to, the first layer of flexible material;

an overlaying flexible material sheet attached to the layer of plastic material by a plurality of seals to form the base sheet and the overlaying sheet into an inflatable covering which has a plurality of interconnected inflatable chambers;

said inflatable chambers in said covering for substantially longitudinal disposition over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body;

an inflating inlet for admitting thermally controlled air into the inflatable chambers to inflate the covering;

a plurality of apertures opening through the base sheet into the chambers for exhausting thermally controlled air from the inflatable chambers through the base sheet in response to inflation and erection of the inflatable covering; and

a seal between the overlaying material sheet and the base sheet around the periphery.

27. (Added) The inflatable thermal blanket of Claim 26,

further including a non-inflatable foot extension formed in the inflatable covering at the second end for enclosing and warming a patient's feet in response to inflation of the inflatable covering.

28. (Added) The inflatable thermal blanket of Claim 27, wherein the non-inflatable foot extension comprises the non-inflatable extension of the inflatable covering beyond the second end.

29. (Added) The inflatable thermal blanket of Claim 27, wherein the non-inflatable foot extension includes an extension of the base sheet beyond the second end.

30. (Added) The inflatable thermal blanket of Claim 27, wherein the plurality of seals are discontinuous elongate seams formed between the overlaying material sheet and the sheet of plastic material.

31. (Added) The inflatable thermal blanket of Claim 30, wherein the discontinuous elongate seams form the overlaying material sheet into the plurality of inflatable chambers, the plurality of inflatable chambers including parallel, communicating tubular chambers.

32. (Added) The thermal blanket of Claim 30, wherein the non-inflatable foot extension includes an extension of the base sheet beyond the second end.

33. (Added) A thermal care system including the inflatable thermal blanket of Claim 27, and further including:

a heater/blower assembly for providing a source of heated air; and

a connecting hose coupled to the heater/blower assembly and to the inflating inlet for conducting heated air from the heater/blower assembly into the inflatable covering.

34. (Added) A method of warming a person using a thermal blanket including an inflatable space formed between a flexible base sheet and an overlaying material sheet attached to the base sheet by a peripheral seal around the periphery of the thermal blanket and a plurality of seals inside the periphery of the thermal blanket that form the base sheet and overlaying material sheet into an inflatable covering with a plurality of interconnected inflatable chambers, and apertures that open into the inflatable space through the flexible base sheet for exhausting air from the inflatable space, the method comprising the steps of:

disposing the thermal blanket to substantially longitudinally dispose the inflatable chambers over a portion of a patient's body extending substantially from the pelvic area of said patient's body to the feet of said patient's body; inflating the thermal blanket with warmed air; and exhausting warmed air through the apertures in the flexible sheet.

35. (Added) The method of Claim 34, wherein the thermal blanket further includes a non-inflatable section formed in a portion of the periphery of the thermal blanket, the method further comprising the steps of:

the non-inflatable section forming a non-inflatable foot drape in the thermal blanket during the inflating step; and using the non-inflatable foot drape, trapping and retaining the heat under the thermal blanket during the exhausting step.

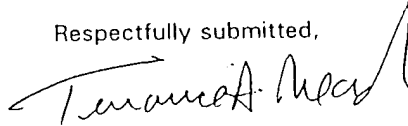
Remarks

The applicants enclose a copy of page 671 of the Ninth New

Collegiate Dictionary for reference respecting the term "laminated to"
which is supported in the originally-filed application at page 11, line
29.

The applicants now await the first examination in this
application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Terrance A. Meador", with a stylized flourish at the end.

TERRANCE. A. MEADOR
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 2770
San Diego, California 92101

Phone: 619/233-9004
Fax: 619/544-1246

SEP 2 1995



Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Baker, Maxham, Jester & Meador

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/419,719 04/10/95 AUGUSTINE

F3M1/0914

TERRANCE A MEADOR
BAKER MAXHAM JESTER & MEADOR
SYMPHONY TOWERS
750 B STREET SUITE 2770
SAN DIEGO CA 92101

1342-119

EXAMINER

GRAHAM, M

ART UNIT

PAPER NUMBER

3304

DATE MAILED:

09/14/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined☒ Responsive to communication filed on 9/10/95☒ This action is made final

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☒ PTO 152

Part II SUMMARY OF ACTION

1. ☒ Claims 1-3, 8-10 are pending in the application.

Of the above, claims are withdrawn from consideration.

2. ☐ Claims have been cancelled.

3. ☐ Claims are allowed.

4. ☒ Claims 1-3, 8-10 are rejected.

5. ☐ Claims are objected to.

6. ☐ Claims are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
--------------------	-------------	-----------------------	------------------------

DATE MAILED:

NOTICE OF INFORMAL APPLICATION

(Attachment to Office Action)

This application does not conform with the rules governing applications for the reason(s) checked below. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action.

A. A new oath or declaration, identifying this application by the application number and filing date is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:

1. ☐ does not identify the city and state or foreign country of residence of each inventor.
2. ☐ does not identify the citizenship of each inventor.
3. ☐ does not state whether the inventor is a sole or joint inventor.
4. ☐ does not state that the person making the oath or declaration:
 - a. ☐ has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
 - b. ☐ believes the named inventor or inventors to be the original and the first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
 - c. ☐ acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.
5. ☐ does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.
6. ☐ does not state that the person making the oath or declaration acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and filing date of the continuation-in-part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)).
7. ☐ does not include the date of execution.
8. ☐ does not use permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).
9. ☐ contains non-initialed alterations (See 37 CFR 1.52(c)).
10. ☐ Other:

B. Applicant is required to provide:

1. ☐ A statement signed by applicant giving his or her complete name. A full name must include at least one given name without abbreviation as required by (37 CFR 1.41(a)).
2. ☐ Proof of authority of the legal representative under 37 CFR 1.44.
3. ☐ An abstract in compliance with 37 CFR 1.72(b).
4. ☐ A statement signed by applicant giving his or her complete post office address (37 CFR 1.33(a)).
5. ☐ A copy of the specification written, typed, or printed in permanent ink, or its equivalent in quality as required by 37 CFR 1.52(a).

6. ☒ Other:

A LABEL FOR DRAWING FIGURES 2, 5, 7, 9
& 11

FORM PTO-892
(REV. 2-92)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

SERIAL NO.

GROUP/ART. UNIT

ATTACHMENT
TO
PAPER
NUMBER

3

NOTICE OF REFERENCES CITED

APPLICANT(S)

Augustine et al.

U.S. PATENT DOCUMENTS

		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
A	2	110022	3/58	Kierath	107	107	
B	4	660388	4/87	Greene	5	485	
C	4	572188	2/86	Augustine	107	107	
D	5	324320	6/94	Augustine et al.	607	107	5/20/91
E	4	807644	2/89	Soldhaus	128	853	
F							
G						152	
H							
I							
J							
K							

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG.	PP. SPEC.
L									
M									
N									
O									
P									
Q									

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

R	
S	
T	
U	

EXAMINER

Graham

DATE

9/8/95

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05(a).)

Art Unit: 3304

Claims 1-3 and 8-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claims 1 and 8 both recite that the blanket is "sized to extend" across a certain portion of a patients body. Obviously this is a dimension which would vary from patient to patient thus leaving the limits on the claims unclear.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 8 and 9 are rejected under 35 U.S.C. § 103 as being unpatentable over Kliesrath in view of Augustine^{1,113} for the reasons set forth in the 11/5/91 rejection of the parent application.

Claim 10 is rejected under 35 U.S.C. § 103 as being unpatentable over the art as applied to claim 8 above, and

further in view of Sandhaus for the reasons set forth in the 11/5/91 rejection of the parent application.

Claims 1 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,324,320. Although the conflicting claims are not identical, they are not patentably distinct from each other because sizing the '320 blanket to fit various areas of the body would have been obvious to one of ordinary skill in the art.

Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,324,320 in view of Kliesrath for the reasons set forth in the 11/5/91 rejection of the parent application.

Claims 3 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,324,320 in view of Sandhaus for the reasons set forth in the 11/5/91 rejection of the parent application.

Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,324,320 in view of Greene for the reasons set forth in the 11/5/91 rejection of the parent application.

Art Unit: 3304

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

This is a continuation of applicant's earlier application S.N. 07/638,748. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Serial Number: 08/419,719

-5-

Art Unit: 3304

Any inquiry concerning this communication should be directed
to Mark S. Graham at telephone number (703) 308-1355.

MSG
September 8, 1995

MARK S. GRAHAM
PRIMARY EXAMINER
GROUP 3300

The USPTO date stamp hereon will acknowledge receipt of:

INFORMATION DISCLOSURE STATEMENT for "Thermal Blanket" (2 pgs)

Applicant: Scott D. Agusutine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995

Mailed: August 8, 1995

Enclosed: PTO 1449 and listed Williams Reference
Copies of Information Disclosure Statements
for 07/550,757, 07/227,189, and 07/104,682
Change of Address Notification

TAM/cmr
1342-119

The USPTO date stamp hereon will acknowledge receipt of:

INFORMATION DISCLOSURE STATEMENT for "Thermal Blanket" (2 pgs)

Applicant: Scott D. Agusutine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
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for 07/550,757, 07/227,189, and 07/104,682
Change of Address Notification

TAM/cmr
1342-119



82

"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
S.D. Augustine et al) Group No.: 3311
Serial No.: 08/419,719)
Filed: April 10, 1995) Examiner: Unknown
For: THERMAL BLANKET)

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below:	
8/8/95 Date	Tenance A. Reed Signature

Dear Sir:

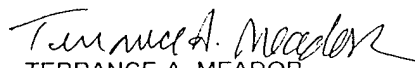
INFORMATION DISCLOSURE STATEMENT

In satisfaction of their duty of candor and fair dealing, the
applicants hereby cite the documents listed on the accompanying PTO-
1449 forms (copies enclosed) which were submitted in the parent
application (07/550,757, 07/227,189, and 07/104,682) of the above-
identified patent application under the provisions of 37 CFR, Sections
1.56, 1.97, and 1.98. A form PTO 1449 for this application is also

enclosed together with a legible copy of the reference which it lists (U.S. Patent No. 2,512,559).

The filing of this Information Disclosure Statement should not be construed to mean that a search was conducted or that no other material information, as defined by 37 CFR 1.56, exists. The Examiner is respectfully requested to make of record what he deems relevant to the examination of this application.

Respectfully submitted,


TERRANCE A. MEADOR
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

Phone: 619/233-9004
Fax: 619/544-1246

Form PTO-1449

**INFORMATION DISCLOSURE CITATION
IN AN APPLICATION**
(Use Several Sheets If Necessary)

Docket No. 1342-119

Application No. 08/419,719

Applicant: S.D. Augustine et al

Filing Date: 4/10/95

Group Art Unit 3311

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2,512,559	6/20/50	Williams	5	347	1/18/45

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

(2/92 PTO)

Sheet 1 of 1

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
SCOTT D. AUGUSTINE ET AL)	
)	
Serial No: 227,189)	Group Art Unit: 334
)	
Filed: August 2, 1988)	
)	
For: THERMAL BLANKET)	Examiner: Unknown
)	
)	

INFORMATION DISCLOSURE STATEMENT

In satisfaction of the duty of disclosure, the
applicants hereby submit a copy of a Search Report

I hereby certify that correspondence
is being deposited with the United States
Postal Service as first class mail in an
envelope addressed to the Commissioner of
Patents and Trademarks, Washington, D.C.
20530 on February 24, 1989

TERRANCE A. MEADOR

(Applicant, Attorney, or Agent)

(Representative)

Terrance A. Meador

(Signature)

February 24, 1989

(Date of Signature)

returned in European Patent Application No. EPO 88309191.0. This EPO application claims priority of the parent of this application, U.S. Patent Application Serial No. 07/104,682, filed October 5, 1987, for "THERMAL BLANKET", which is now abandoned, and the identified application.

The Search Report indicates that all of the references found by the Examiner form the technological background of the invention. In addition, U.S. Patent No. 4,572,188 is designated as being cited in the application.

Also disclosed are the three references returned with the European Search Report. The first reference, U.S. Patent 4,572,188 has already been cited and discussed in the preliminary amendment to this application, submitted October 10, 1988.

The German Patent DE3308553 was provided without translation; the applicants do not have an English translation of this patent. From the figures, the patent appears to cover a vest with a series of tubular chambers, which might be inflated when the vest is in use.

U.S. Patent 3,714,947 describes a baby blanket designed to control hypothermia and consisting of an envelope having an upper portion with a provision for circulating a temperature-controlled fluid through the

blanket.

The Examiner is requested to consider these references
and to make of record those deemed to be material to
examination of this application.

Respectfully submitted,

Terrance A. Meador

TERRANCE A. MEADOR
Attorney for Applicant(s)
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
110 West "C" Street, Suite 1202
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PTO-1449
7-1991U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

Sheet 1 of 1

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(Use several sheets if necessary)

ATTY. DOCKET NO.

0545-PA09

SERIAL NO.

07/227,189

APPLICANT

SCOTT D. AUGUSTINE ET AL

FILING DATE

8/2/88

GROUP

334

U.S. PATENT DOCUMENTS

IN- NER L		DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	3	7	1	4	9	4	7		02/06/73	HARDY	128	400	02/11/71
	AB	4	5	7	2	1	8	8		02/25/86	AUGUSTINE ET AL	128	380	03/05/84
	AC													
	AD													
	AE													
	AF													
	AG													
	AH													
	AI													
	AJ													
	AK													

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
														YES	NO
	AL	3	3	0	8	5	5	3			Smidt	A61F7/00			X
	AM														
	AN														
	AO														
	AP														

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	Search Report in EPO Patent Application EPO 88309191.0
	AS	
	AT	

AMINER

DATE CONSIDERED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
SCOTT D. AUGUSTINE ET AL)	
Serial No: 07/104,682)	Group Art Unit: 334
Filed: August 2, 1988)	
For: THERMAL BLANKET)	Examiner: Unknown
)	
)	

INFORMATION DISCLOSURE STATEMENT

In satisfaction of the applicants' duty of candor and fair dealing, disclosure is made of issued United States Patents relating to body warming.

I hereby certify that this correspondence
is being deposited with the United States
Postal Service as first class mail in an
envelope addressed to: Commissioner of
Patents and Trademark, Washington, D.C.
20231 on April 25, 1989

TERRANCE A. MEADOR

(Applicant, Assignee, Registered
Representative)

Terrance A. Meador

(Signature)

April 25, 1989

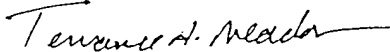
(Date of Signature)

The disclosed patents represent the result of a patentability search conducted on an invention made by the applicants for which a patent application has not yet been filed.

The information disclosed hereby carries no implication that other information, more material to the invention described and claimed in the identified application, does not exist.

The Examiner is requested to review these patents and to make of record those which are considered to be material to examination of this application.

Respectfully submitted,


TERRANCE A. MEADOR
Attorney for Applicant(s)
Registration No. 30,298

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110 West "C" Street, Suite 1202
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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(Use several sheets if necessary)

ATTY. DOCKET NO. 0545PA-09	SERIAL NO. 07/227,189
APPLICANT SCOTT D. AUGUSTINE, ET AL	
FILING DATE August 2, 1988	GROUP 334

U.S. PATENT DOCUMENTS

AMINER TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	2 2 2 6 9 0	Dec. 16, 1879	S. GOLDSCHMIDT	128	403	07/21/1879
	AB	1 3 9 9 0 9 5	Dec. 6, 1921	J.F. WEBB, SR.	128	402	12/02/19
	AC	1 7 7 7 9 8 2	Oct. 7, 1930	K. POPP	128	399	06/10/29
	AD	2 0 9 3 8 3 4	Sept 21, 1937	R.S. GAUGLER	128	402	04/30/34
	AE	2 6 0 1 1 8 9	June 17, 1952	N.B. WALES, JR.	4	160	08/22/49
	AF	2 7 0 6 9 8 8	Apr. 26, 1955	H. WEBER	128	402	09/15/52
	AG	3 4 1 8 7 2 6	Dec. 31, 1968	W.E. SPARKS	34	99	12/19/66
	AH	3 6 1 0 2 5 1	Oct. 5, 1971	A.C. SANDERSON	128	379	07/14/69
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL							
	AM							
	AN							
	AO							
	AP							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	
	AS	
	AT	

EXAMINER

DATE CONSIDERED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
SCOTT D. AUGUSTINE)	
Serial No: 07/550,757)	Group Art Unit:
Filed: July 10, 1990)	334
For: THERMAL BLANKET)	Examiner:
)	M. Graham
)	

Commissioner of Patents and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

In satisfaction of the duty of candor and fair
dealing, the applicants hereby disclose the publication
listed on the attached Form 1449.

I hereby certify that this correspondence
is being deposited with the United States
Postal Service as first class mail in an
envelope addressed to: Commissioner of
Patents and Trademarks, Washington, D.C.
20231 on August 23, 1991.

TERRANCE A. MEADOR

(Applicant or Agent)

Terrance A. Meador

(Signature)

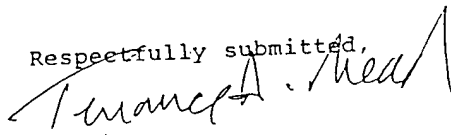
August 23, 1991

(Date of Signature)

The listed reference is a copy of European Patent Application 88309191.0 which was published on May 12, 1989. This European application corresponds to, and claims priority from, the applications identified as parents of the application identified in the caption of this paper.

The Examiner is requested to review the reference and, if deemed material to the examination of this application, to make it of record in the file.

Respectfully submitted,



TERRANCE A. MEADOR
Attorney for Applicant
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
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San Diego, California 92101

Telephone: (619) 233-9004

Sheet 1 of 1

FORM PTO-1449 (Rev. 2-82)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 547		SERIAL NO. 07 / 550,757
		APPLICANT Scott D. Augustine		
		FILING DATE 7/10/90	GROUP 334	

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

[illegible]

EXAMINER	DATE CONSIDERED
EXAMINER	

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
)
S.D. Augustine et al) Group No.: 3311
)
Serial No.: 08/419,719)
) Examiner: Unknown
Filed: April 10, 1995)
)
For: THERMAL BLANKET)

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

CERTIFICATE OF MAILING	
37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below:	
8/8/95	<i>Terrance A. Meador</i>
Date	Signature

Dear Sir:

CHANGE OF ADDRESS

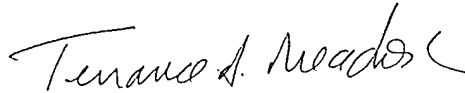
This is to notify the Office that all correspondence in the
subject matter should be addressed to:

Terrance A. Meador
BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

Please direct all telephone calls and facsimile transmissions to:

Terrance A. Meador
Phone: 619/233-9004
Fax: 619/544-1246

Respectfully,

A handwritten signature in black ink, reading "Terrance A. Meador" with a stylized flourish at the end.

Terrance A. Meador
Registration No.: 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 3100
San Diego, California 92101

The USPTO date stamp hereon will acknowledge receipt of:

PRELIMINARY AMENDMENT for "Thermal Blanket" (6 pages)

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995
Mailed: July 7, 1995
Enclosed: Copy of page 671 of Dictionary

TAM/cmr
1342-119

The USPTO date stamp hereon will acknowledge receipt of:

PRELIMINARY AMENDMENT for "Thermal Blanket" (6 pages)

Applicant: S.D. Augustine et al
Assignee: Augustine Medical, Inc.
Serial No.: 08/419,719
Filed: April 10, 1995
Mailed: July 7, 1995
Enclosed: Copy of page 671 of



RECEIVED

AUG 04 1995

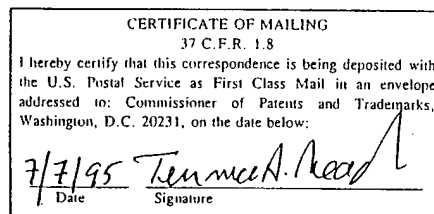
TAM/cmr
1342-119

"PATENT"

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
SCOTT D. AUGUSTINE) Group No.: 3311
Serial No.: 08/419,719)
Filed: April 10, 1995) Examiner: Unknown
For: THERMAL BLANKET)

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231



Dear Sir:

PRELIMINARY AMENDMENT

Prior to the first examination, please amend the above-identified
patent application as follows:

IN THE ABSTRACT

Please cancel the recitation of the Abstract and substitute the
following therefor:

--A thermal blanket includes an inflatable covering
with a head end, a foot end, two edges, and an
undersurface. The covering includes a plurality of
inflatable chambers that are inflated when a thermal-

controlled inflating medium is introduced into the thermal blanket through an inlet at the foot end. When inflated, the thermal blanket self-erects into a structure and provides a bath of thermally-controlled inflating medium to the interior of the erected structure through an aperture array on the undersurface of the inflatable covering. The thermal blanket is constructed for substantially longitudinal disposition over a portion of a patient's body extending from the pelvic area to the feet of the patient's body. Provision may be made for securing the inflatable covering to the patient's body at the head end. Provision may further be made for an uninflatable foot drape at the foot end.--

IN THE DESCRIPTION

Page 9, line 26, please change "20" to --10--.

Page 20, line 2, please change "heater" to --connecting--;

line 3, please change each occurrence of "tube" to --hose--; and

line 18, please change "heater tube" to --connecting hose--.

IN THE CLAIMS

The cancellation of Claims 4-7 and 11-25 in the transmittal of this application on April 10, 1995 is confirmed. Please cancel Claims 1-3 and 8-9. Please add the following claims:

- 1 26. (Added) An inflatable thermal blanket for covering and
- 2 bathing a portion of a patient's body with thermally-controlled air,

3 comprising:

4 a flexible base sheet having a first end forming a first end

5 of the thermal blanket, a second end forming a second end of

6 the thermal blanket, two edges forming respective edges of the

7 thermal blanket, and an undersurface forming an undersurface

8 of the thermal blanket;

9 the first end, the second end, and respective edges of the

0 base sheet forming a periphery of the thermal blanket;

1 the base sheet including a first layer of flexible material

2 and a second layer of plastic material co-extensive with, and

3 laminated to, the first layer of flexible material;

4 an overlaying flexible material sheet attached to the layer

5 of plastic material by a plurality of seals to form the base sheet

6 and the overlaying sheet into an inflatable covering which has a

7 plurality of interconnected inflatable chambers;

8 said inflatable chambers in said covering for substantially

9 longitudinal disposition over a portion of a patient's body

0 extending substantially from the pelvic area of said patient's

1 body to the feet of said patient's body;

2 an inflating inlet for admitting thermally controlled air into

3 the inflatable chambers to inflate the covering;

4 a plurality of apertures opening through the base sheet

5 into the chambers for exhausting thermally controlled air from

6 the inflatable chambers through the base sheet in response to

7 inflation and erection of the inflatable covering; and

8 a seal between the overlaying material sheet and the base

9 sheet around the periphery.

1 27. (Added) The inflatable thermal blanket of Claim 26,

2 further including a non-inflatable foot extension formed in the
3 inflatable covering at the second end for enclosing and warming a
4 patient's feet in response to inflation of the inflatable covering.

1 28. (Added) The inflatable thermal blanket of Claim 27,
2 wherein the non-inflatable foot extension comprises the non-inflatable
3 extension of the inflatable covering beyond the second end.

1 29. (Added) The inflatable thermal blanket of Claim 27,
2 wherein the non-inflatable foot extension includes an extension of the
3 base sheet beyond the second end.

1 30. (Added) The inflatable thermal blanket of Claim 27,
2 wherein the plurality of seals are discontinuous elongate seams
3 formed between the overlaying material sheet and the sheet of plastic
4 material.

1 31. (Added) The inflatable thermal blanket of Claim 30,
2 wherein the discontinuous elongate seams form the overlaying
3 material sheet into the plurality of inflatable chambers, the plurality of
4 inflatable chambers including parallel, communicating tubular
5 chambers.

1 32. (Added) The thermal blanket of Claim 30, wherein the
2 non-inflatable foot extension includes an extension of the base sheet
3 beyond the second end.

1 33. (Added) A thermal care system including the inflatable
2 thermal blanket of Claim 27, and further including:

3 a heater/blower assembly for providing a source of
4 heated air; and

5 a connecting hose coupled to the heater/blower assembly
6 and to the inflating inlet for conducting heated air from the
7 heated/blower assembly into the inflatable covering.

1 34. (Added) A method of warming a person using a thermal
2 blanket including an inflatable space form between a flexible base
3 sheet and an overlaying material sheet attached to the base sheet by a
4 peripheral seal around the periphery of the thermal blanket and a
5 plurality of seals inside the periphery of the thermal blanket that form
6 the base sheet and overlaying material sheet into an inflatable
7 covering with a plurality of interconnected inflatable chambers, and
8 apertures that open into the inflatable space through the flexible base
9 sheet for exhausting air from the inflatable space, the method
0 comprising the steps of:

1 disposing the thermal blanket to substantially
2 longitudinally dispose the inflatable chambers over a portion of
3 a patient's body extending substantially from the pelvic area of
4 said patient's body to the feet of said patient's body;
5 inflating the thermal blanket with warmed air; and
6 exhausting warmed air through the apertures in the
7 flexible sheet.

1 35. (Added) The method of Claim 34, wherein the thermal
2 blanket further includes a non-inflatable section formed in a portion of
3 the periphery of the thermal blanket, the method further comprising
4 the steps of:

5 the non-inflatable section forming a non-inflatable foot
6 drape in the thermal blanket during the inflating step; and
7 using the non-inflatable foot drape, trapping and retaining
8 the heat under the thermal blanket during the exhausting step.

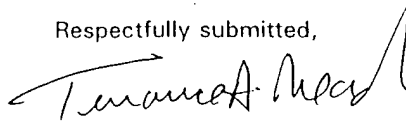
Remarks

The applicants enclose a copy of page 671 of the Ninth New

Collegiate Dictionary for reference respecting the term "laminated to" which is supported in the originally-filed application at page 11, line 29.

The applicants now await the first examination in this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Terrance A. Meador", with a long, sweeping flourish extending to the right.

TERRANCE. A. MEADOR
Registration No. 30,298

BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 2770
San Diego, California 92101

Phone: 619/233-9004
Fax: 619/544-1246

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MAY 05 1995

Baker, Maxham, Jaster & Meador



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
08/419,719	04/10/95	3311	\$365.00	1342-119	5	6	2

TERRANCE A MEADOR
BAKER MAXHAM JESTER & MEADOR
SYMPHONY TOWERS
750 B STREET SUITE 2770
SAN DIEGO CA 92101

Receipt is acknowledged of this patent application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Application Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

Applicant(s)

SCOTT D. AUGUSTINE, BLOOMINGTON, MN; RANDALL C. ARNOLD,
MAPLEWOOD, MN.

CONTINUING DATA AS CLAIMED BY APPLICANT-

THIS APPLN IS A CON OF 07/638,748 01/08/91 PAT 5,405,371
WHICH IS A CIP OF 07/550,757 07/10/90
WHICH IS A CIP OF 07/227,189 08/02/88
WHICH IS A CIP OF 07/104,682 10/05/87 ABN

FOREIGN FILING LICENSE GRANTED 05/01/95
TITLE
THERMAL BLANKET

* SMALL ENTITY *

PRELIMINARY CLASS: 607

(see reverse)

000 U.S.P.T.O.
 UCH DATE DESCRIPTION
 729 04/10/95 1342-119 CONTINUATION PA

CASE
 1342119

12189
 AMOUNT
 365.00

04/10/95 TOTAL PAID 365.00

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Continuation Patent Application Encl

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The USPTO date stamp hereon will acknowledge receipt of: Blanket"

1.60 CONTINUATION PATENT APPLICATION for "Thermal Blanket"

Applicant: Scott D. Augustine et al
 Assignee: Augustine Medical, Inc. 24030US

Mailed: EXPRESS MAIL April 10, 1995 TB 24030US

Enclosed: Transmittal (in duplicate)
 Specification (23 pgs)
 Claims (9 pgs)
 Abstract (2 pgs)
 Drawings (5 sheets)
 Small Entity Statement (copy)
 Declaration/Power of Attorney (copy)
 Express Mail Certification
 Check for \$365

TAM/cmr
 1342-119



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on the date indicated above and is
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and Trademarks, Washington, D.C. 20231.

CLARE M. ROBERTS

(Name)

Clare M. Roberts

(Signature)

REQUEST FORM FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60

(2-92)
DATE: April 10, 1995

DOCKET NUMBER	ANTICIPATED CLASSIFICATION OF THIS APPLICATION		PRIOR APPLICATION EXAMINER	ART UNIT
1342-119	CLASS:	SUBCLASS:	M. GRAHAM	3304

Address to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

This is a Request for filing a *continuation* application under 37 CFR 1.60, of pending application Number 07/638,748, filed January 18, 1991 entitled "THERMAL BLANKET"

Enclosed is a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication it was signed. I hereby verify that the papers are a true copy of the latest signed prior application number 07/638,748, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like are made punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS	6 - 20 -		x \$ 22.00 -	\$
	INDEPENDENT CLAIMS	2 - 3 -		x \$ 76.00 -	\$
	MULTIPLE DEPENDENT CLAIMS (if applicable)			+ \$ 240.00 -	\$
				BASIC FEE	\$ 730.00
				Total of above Calculations -	\$ 365.00
	Reduction by 50% for filing a Small Entity (Note 37 CFR 1.9, 1.27, 1.28).				
				TOTAL =	\$ 365.00

2. ☒ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27
☐ is enclosed.
☒ was filed in prior application number 07/638,748 and such status is still proper and desired (37 CFR 1.28(a)).
3. ☒ The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 02-0460. A duplicate copy of this sheet is enclosed.
4. ☒ A check in the amount of \$365.00 is enclosed.
5. ☒ Cancel in this application original claims 4-7, 11-25 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
6. ☒ Amend the specification by inserting before the first line the sentence: "This application is a *continuation* of application number 07/638,748, filed January 8, 1991, (status: pending)."
7. ☐ Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application. (May only be used if signed by person authorized by 37 CFR 1.138 and before payment of issue fee.)

8. ☐ New formal drawings are enclosed.

(2-92)

[Page 1 of 2]

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

TAMPTOI1342-119.160

9. ☐ Priority of foreign application number _____, filed on _____ in _____ is claimed under 35 U.S.C. 119.
☐ The certified copy has been filed in prior application number _____, filed _____.

10. ☐ A preliminary amendment is enclosed.

11. ☒ The prior application is assigned of record to AUGUSTINE MEDICAL, INC.

12. ☐ Also enclosed:

13. ☒ The power of attorney in the prior application is to:

Terrance A. Meador
 BAKER, MAXHAM, JESTER & MEADOR
 110 West "C" Street, Suite 1202
 San Diego, California 92101

- a. ☒ The power of attorney appears in the original papers in the prior application.
 b. ☐ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
 c. ☒ Address all future correspondence to: (May only be completed by applicant, or attorney or agent of record.)

Terrance A. Meador
 BAKER, MAXHAM, JESTER & MEADOR
 Symphony Towers
 750 "B" Street, Suite 2770
 San Diego, California 92101

April 10, 1995
 Date

Terrance A. Meador
 Signature

☐ Inventor(s)
☐ Assignee of complete interest
☒ Attorney or agent of record
☐ Filed under 37 CFR 1.34(a)
 Registration number if acting under 37 CFR 1.34(a). _____

TERRANCE A. MEADOR (30,298)
 Typed or printed name (& registration number if applicable)

REQUEST FORM FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60

(2-92)
DATE: April 10, 1995

DOCKET NUMBER	ANTICIPATED CLASSIFICATION OF THIS APPLICATION		PRIOR APPLICATION EXAMINER	ART UNIT
	CLASS:	SUBCLASS:		
342-119			M. GRAHAM	3304

Address to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

This is a Request for filing a *continuation* application under 37 CFR 1.60, of pending application Number 07/638,748, filed January 18, 1991 entitled "HERMAL BLANKET"

I enclose a copy of the latest inventor-signed prior application, including a copy of the oath or declaration showing the original signature or an indication was signed. I hereby verify that the papers are a true copy of the latest signed prior application number 07/638,748, and further that all statements made herein of my own knowledge are true; and further that these statements were made with the knowledge that willful false statements and the like are made punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the application or any patent issuing thereon.

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS	6 - 20 -		x \$ 22.00 -	\$
	INDEPENDENT CLAIMS	2 - 3 -		x \$ 76.00 -	\$
	MULTIPLE DEPENDENT CLAIMS (if applicable)			+ \$ 240.00 -	\$
				BASIC FEE	\$ 730.00
				Total of above Calculations -	\$ 365.00
	Reduction by 50% for filing a Small Entity (Note 37 CFR 1.9, 1.27, 1.28).				
	TOTAL =				\$ 365.00

- ☒ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.
☒ was filed in prior application number 07/638,748 and such status is still proper and desired (37 CFR 1.28(a)).
- ☒ The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 02-0460. A duplicate copy of this sheet is enclosed.
- ☒ A check in the amount of \$365.00 is enclosed.
- ☒ Cancel in this application original claims 4-7, 11-25 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
- ☒ Amend the specification by inserting before the first line the sentence: "This application is a *continuation* of application number 07/638,748, filed January 8, 1991, (status: pending)."
- ☐ Transfer the drawings from the pending prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application. (May only be used if signed by person authorized by 37 CFR 1.138 and before payment of issue fee.)

☐ New formal drawings are enclosed.

(2-92)

[Page 1 of 2]

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

TAMPTO1342-119.160

REQUEST FORM FOR FILING A PATENT APPLICATION UNDER 37 CFR 1.60, Page 2)

DOCKET NO.: 1342-119

9. ☐ Priority of foreign application number _____ filed on _____ in _____ is claimed under 35 U.S.C. 119.
_____ The certified copy has been filed in prior application number _____ filed _____.

10. ☐ A preliminary amendment is enclosed.

11. ☒ The prior application is assigned of record to AUGUSTINE MEDICAL, INC.

12. ☐ Also enclosed:

13. ☒ The power of attorney in the prior application is to:

Terrance A. Meador
BAKER, MAXHAM, JESTER & MEADOR
110 West "C" Street, Suite 1202
San Diego, California 92101

- a. ☒ The power of attorney appears in the original papers in the prior application.
b. ☐ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
c. ☒ Address all future correspondence to: (May only be completed by applicant, or attorney or agent of record.)

Terrance A. Meador
BAKER, MAXHAM, JESTER & MEADOR
Symphony Towers
750 "B" Street, Suite 2770
San Diego, California 92101

April 10, 1995
Date

Terrance A. Meador
Signature

☐ Inventor(s)
☐ Assignee of complete interest
☒ Attorney or agent of record
☐ Filed under 37 CFR 1.34(a)
☐ Registration number if acting under 37 CFR 1.34(a) _____

TERRANCE A. MEADOR (30,298)
Typed or printed name (& registration number if applicable)

ant or Patentee: SCOTT D. AUGUSTINE, ET AL. (Attorney's
or Patent No.: Unknown Docket No.: 0603
or Issued: Herewith
"THERMAL BLANKET"

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN

I declare that I am
[] the owner of the small business concern identified below:
[x] an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN AUGUSTINE MEDICAL, INC.
ADDRESS OF CONCERN 10393 West 70th Street, Suite 100, Eden Prairie, MN 55344

I declare that the above identified small business concern qualifies as a small business
as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying
fees under section 41(a) and (b) of Title 35, United States Code, in that the number of
employees of the concern, including those of its affiliates, does not exceed 500 persons. For
purposes of this statement, (1) the number of employees of the business concern is the average over
the previous fiscal year of the concern of the persons employed on a full-time, part-time or tempo-
rary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of
each other when either, directly or indirectly, one concern controls or has the power to control the
other or a third party or parties controls or has the power to control both.

I declare that rights under contract or law have been conveyed to and remain with the small
business concern identified above with regard to the invention, entitled "THERMAL BLANKET"
by inventor(s) SCOTT D. AUGUSTINE and RANDALL C. ARNOLD

[x] the specification filed herewith
application serial no. _____, filed _____
patent no. _____, issued _____

rights held by the above identified small business concern are not exclusive, each indivi-
dual concern or organization having rights to the invention is listed below* and no rights to the
invention are held by any person, other than the inventor, who could not qualify as a small business
concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern
under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

NOTE: Separate verified statements are required from each named person, concern,
or organization having rights to the invention averring to their status as
small entities. (37 CFR 1.27).

WE
[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

WE
[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status
resulting in loss of entitlement to small entity status prior to paying, or at the time of paying,
the fee of the issue fee or any maintenance fee due after the date on which status as a small
entity is no longer appropriate. (37 CFR 1.28(b)).

I declare that all statements made herein of my own knowledge are true and that all state-
ments made on information and belief are believed to be true; and further that these statements were
made with the knowledge that willful false statements and the like so made are punishable by fine or
imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such
false statements may jeopardize the validity of the application, any patent issuing thereon,
or patent to which this verified statement is directed.

* PERSON SIGNING SCOTT D. AUGUSTINE
IF PERSON OTHER THAN OWNER President
ADDRESS OF PERSON SIGNING 10393 West 70th Street, Ste. 100, Eden Prairie, MN 55344

THERMAL BLANKET

RELATED APPLICATIONS

This is a continuation-in-part of application serial no. 07,550,757, filed July 10, 1990, which is a continuation-in-part of application serial no. 07,227,189, filed August 2, 1988, which is a continuation-in-part of application serial no. 07,104,682, filed October 5, 1987.

BACKGROUND OF THE INVENTION

This invention relates to thermal blankets used in a medical setting to deliver a bath of a thermally-controlled medium to a patient.

The thermal blanket prior art is best expressed in our prior U.S. Patent No. 4,572,188 entitled "AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE." In our prior patent, a self-erecting, inflatable airflow cover is inflated by the introduction into the cover of a thermally-controlled inflating medium, such as warmed air. When inflated, the cover self-erects about a patient, thereby creating an ambient environment about the patient, the thermal characteristics of which are determined by the temperature of the inflating medium. Holes on the underside of our prior art airflow cover exhaust the thermally-controlled, inflating medium from inside the cover to the interior of the erected structure. Our airflow cover is intended for the treatment of hypothermia, as might occur postoperatively.

Evaluation of our airflow cover by skilled practitioners has resulted in general approbation: the opinion is that the airflow cover efficiently and effectively accomplishes its purpose of giving a thermally-controlled bath. We have realized, however, that, while our prior art airflow cover achieves its objective, certain improvements to it are necessary in order to realize additional clinical objectives and to enjoy further advantages in its use.

SUMMARY OF THE INVENTION

We have improved the clinical usefulness of our self-erecting airflow cover by observing that controlling the contour of its inflatable portion at its head end to define a generally concave non-inflatable portion will permit a care giver to more easily observe a patient's head, face, neck and chest. Further, we have observed that limited venting of the thermally controlled inflating medium from the edges of the cover results in more efficient, more uniform heating within the cover. We have also observed that it is good clinical practice to keep the area of the care site in the vicinity of the patient's head and face as clean as possible. Still further, we have observed that modification of the foot end of the self-erecting airflow cover to define a non-inflatable but erectable drape section retains heat from the inflating medium to warm the patient's feet and insulate the bare skin of the feet from excessive heat from the inlet hose. Finally, we have observed that our self-erecting airflow cover may be advantageously adapted to thermally control

specific partial portions of the patient such as the legs and lower body or the arms and upper body, leaving other areas of the patient available for care and treatment. Moreover, an end portion of the cover may be adhesively attached to the patient to prevent the migration of air toward a care area. Finally, a protective sleeve may be slideably mounted on a connected heater tube adjacent the patient to prevent the heater tube from contacting the patient.

These observations have resulted in an improved thermal blanket and method therefor in which a self-erecting inflatable covering has a head end, a foot end, two edges, and an undersurface. An inflating inlet adjacent the foot (or head) end admits a thermally-controlled inflating medium into the covering. An aperture array on the undersurface of the covering exhausts the thermally controlled inflating medium from the covering into the structure created when the covering self-erects upon inflation. The improvements to this basic structural complement include an uninflatable section at the head (or foot) end of the covering, exhaust port openings at the edges of the covering, an absorbent bib or adhesive strip attached to the covering at the head (or foot) end adjacent the uninflatable section, an uninflatable erectable drape section at the foot end of the covering, a heater tube protective cover and structural features that make the covering simple and economical to produce. In the case of an upper body covering, the positions of the inflating inlet and the uninflatable section are reversed from that of other coverings. In the case of an upper body covering, the inflating inlet is positioned at the head end of the

covering while the uninflatable section is arranged at the foot end of the covering.

5 With these improvements, the thermal blanket, when inflated and erected over a patient, delivers the thermally-controlled inflating medium into the interior of the structure covering the patient, thereby thermally bathing the patient. The first improvement permits full viewing of the head and face of the patient from almost any aspect around the thermal blanket. The exhaust port
0 openings increase the rate of circulation of the inflating medium within the blanket, thereby increasing the temperature within the structure and making the temperature distribution more uniform. The absorbent bib soaks up and retains liquids which might otherwise spread over the care site in the area of a patient's head or other body area.
5 Such liquids can include the patient's own perspiration, blood, vomit, saliva, or liquids which are administered to the patient. The adhesive strip acts to seal the head (or foot) end of the inflated structure. The non-inflatable
0 erectable drape section at the foot end of a covering encompassing the lower extremities retains heat around the patient's feet and insulates the bare skin of the legs and/or feet. The protective cover for the heater tube prevents an attached heater tube from contacting the
5 patient.

From another aspect, the invention is a thermal blanket for covering and bathing a person in a thermally-controlled medium. The thermal blanket includes a flexible base sheet having a head end, a foot end, two edges, and a
0 plurality of apertures opening between the first and second surface of the base sheet. An overlying material sheet is

attached to the first surface of the base sheet by a plurality of discontinuous seams which form the material sheet into a plurality of substantially -parallel, inflatable chambers. A continuous seam is provided between the material sheet and the base sheet at the head (or foot) end to form a non-inflatable viewing recess at the head (or foot) end. Exhaust port openings are provided through the material sheet to vent the medium from the chambers away from the base sheet. An absorbent bib is attached to the head (or foot) end in the vicinity of the viewing recess. In coverings encompassing the lower extremities, a continuous seam is provided between the material sheet and the base sheet at the foot end to form a non-inflatable, erectable drape section to cover the patient's legs and/or feet.

Therefore the invention accomplishes the important objective of providing a self-erecting, inflatable thermal blanket that permits a relatively unobstructed view of a care site when in use.

Another objective is the efficient and uniform heating of the interior of the structure created when the blanket is inflated with a heat inflating medium.

A further objective is providing a covering for a patient's legs and/or feet that helps retain the heat inflating medium around the patient.

A still further objective is the provision of such a blanket with a means for maintaining the cleanliness of the care site.

A still further objective is to provide the ability to select coverings adapted for specific partial areas of the patient leaving other areas exposed for care and treatment.

The advantageous simplified structure of the thermal blanket make its production straight forward and economical.

These and other important objectives and advantages will become evident when the detailed description of the invention is read with reference to the below-summarized drawings, in which:

Figure 1 is a side elevation view of a thermal blanket constructed in accordance with a first aspect of the invention, with the blanket in use, with associated thermal apparatus indicated schematically;

Figure 2 is an enlarged top plan view of the thermal blanket opened flat;

Figure 3 is an enlarged sectional view taken along 3-3 of Figure 2;

Figure 4 is a further enlarged sectional view taken along line 4-4 of Figure 3;

Figure 5 is a partial underside view of the thermal blanket;

Figure 6 is a partial diagrammatic top plan view of a thermal blanket constructed in accordance with a second aspect of the invention, with a partially constructed foot drape;

Figure 7 is a partial projected view of a fully constructed thermal blanket of Figure 6 in use, with the patient's feet illustrated by hidden lines underlying the foot drape;

Figure 8 is a top plan view of a partially constructed thermal blanket in accordance with a third aspect of the invention, for thermally covering the pelvic area and lower extremities of a patient;

Figure 9 is a partial projected view of a fully constructed thermal blanket of Figure 8 in use;

Figure 10 is a top plan view of a thermal blanket constructed in accordance with a fourth aspect of the present invention, for thermally covering the chest and upper extremities of a patient; and

Figure 11 is a partial projected view of a fully constructed thermal blanket of Figure 10 in use.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

When used herein, the term "thermal blanket" is intended to be interchangeable with, but not necessarily limited by, the term "airflow cover" used in our U.S. Patent No. 4,572,188, which is incorporated herein in its entirety by reference. In this description, the term "thermal blanket" is meant to invoke a self-erecting, inflatable structure for delivering a thermally-controlled inflating medium to the interior of the structure created when the thermal blanket is inflated. The purpose of the thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within the erected structure.

Our invention is illustrated as we intend for it to be used in a first aspect without a foot drape in Figure 1. In Figure 1, a self-erecting, inflatable thermal blanket 10 has a head end 12, a foot end 14 and two lateral edges, one indicated by 15. An inflation inlet cuff 16 is connected to a heater/blower assembly 18 which provides a stream of heated air through a connecting hose 20. When the heater/blower 18 is operated, the stream of heated air flows through the inflating hose 20 into the thermal blanket 10 through the inflation cuff 16. When the blanket is inflated, it erects itself into a Quonset hut-like structure with a quilted upper surface 21. As described below, a pattern of apertures on the undersurface of the blanket (not shown in Figure 1) convectively delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

The contour of the inflatable portion of the thermal blanket 10 is varied at the head end 12 of the blanket to provide a non-inflated blanket recess 22 in the quilted upper surface 21, which remains smooth and flat when the blanket is inflated and erected. Circulation of the heating air is accelerated through the thermal blanket by exhaust port openings in the upper surface, adjacent the lateral edges of the blanket. Two exhaust ports openings are indicated by reference numeral 23. Further, a bib 24 made of an absorbent material is attached to the head end 12 of the thermal blanket in the vicinity of the non-inflated recess 22. In fact, as shown in Figure 1, the bib 24 includes a semi-circular tab 25 that extends into the recess 22.

As illustrated in Figure 1, the thermal blanket of the invention is inflated, erects itself into a bathing structure, and bathes a patient 26 with the thermally-controlled air used to inflate the structure. While the patient is being thermally bathed, the uninflated recess 22 permits observation of the patient's head, face, neck, and chest from almost any location with respect to the thermal blanket 10. Thus, if the patient is placed on a gurney or a bed, the head of which is against a wall, a care giver such as a nurse, intern, resident, or doctor, can keep the patient's face under observation from the foot end 14 of the thermal blanket 20. Respiration can be detected by the rise and fall of the bib and uninflated area, which rest directly on the patient's chest. Moreover, the bib 24 will provide an absorbent sink for stray, unconfined liquids in the area of the patient's head or at the head end 12 of the thermal blanket 10.

Figure 2 is a plan view of the thermal blanket 10 opened flat to show details of its structure. Figure 2 illustrates the upper surface of the thermal blanket, that is the side that is visible in Figure 1. As seen, the upper surface consists of a parallel array of elongated tubes of which 30 and 32 are the lateralmost tubes, 34 is the center tube, and the tubes 38 are arrayed between one of the lateralmost tubes and the center tube. Each tube is separated from an adjacent tube by a discontinuous seam, one of which is indicated by 40. The seam 40 separates the tube 32 and its nearest adjacent neighbor 38. The discontinuous seam 40 is interrupted by passageways 42 communicating between the tubes. An interrupted seam separates every tube from one adjacent neighboring tube. The seams permit the thermal blanket, when inflated, to assume a tubular structure on the upper surface, while the ports 42 permit full circulation of the inflating medium throughout the array of tubes. The foot-end seam 45 is continuous. The tubes are inflated through the center tube 34 which transitions to a port 36, through which the inflation cuff 16 is inserted. The edge seams 43 are discontinuous only at the exhaust port opening locations 23. A seal can be made between the inflation port 36 and the inflation cuff 16 by any conventional means, for example, an o-ring, or even tape. When the inflating medium is introduced into the center tube 34, it flows laterally from the center tube into all of the other tubes through the ports 42. Near the head end 12, a continuous seam 40 defines the forward end of all of the tubes, with the seam assuming a bell-curve shape. On the head end side of the seam 40, the thermal blanket 10 is uninflatable.

The bell-shaped seam 40 thus defines the uninflatable area 22 at the head end of the thermal blanket 10, which is essentially coplanar with, or substantially parallel to, the underside of the blanket. As shown in Figure 1, by virtue of its structural integration with the rest of the thermal blanket 10, the non-inflated recess extends over the upper chest of the patient 26 when the blanket is inflated. However, since the recess 22 is uninflated, it provides a wide-angled viewing gap in the inflated contour of the upper surface 21. The gap is filled by continuation of the underside of the blanket. It is also noted that the pattern of inflatable tubes can be replaced by other suitable patterns of communicating, inflatable chambers. The tubes are preferred since they impart strength and shape to the erected bathing structure; other inflatable structures are contemplated, however.

The absorbent bib has an indent 44 cut into its outside edge, which permits the blanket to be drawn up to the chin of a patient and which provides absorbency laterally up the neck of the patient. The absorbent bib can consist of any absorbent material such as a single- or multi-ply tissue paper which is used to make paper towels.

Construction details of the thermal blanket 10 are illustrated in Figures 3 and 4. The thermal blanket 10 is assembled from a base sheet consisting of an underside layer 50 formed from flexible material capable of bonding to a layer 52 of heat-sealable plastic. For the layers 50 and 52, we have used a stratum of absorbent tissue paper prelaminated with a layer of heat-sealable plastic. Material of such construction is commercially available in production rolls and is used to make painters' drop

cloths. The upper side of the thermal blanket consists of a sheet of plastic bonded to the plastic layer 52 by an interruptible heat-sealing process to form the interrupted seams, one of which is indicated by 54, and the inflatable tubes, one indicated by 55. As can be seen in Figure 3, the interruption of the seam 54 forms a passageway 56 between adjacent tubes 55 and 57.

The absorbent bib and tab are shown in Figure 3 as a single material layer 60/58. Alternatively, they may be formed from separate material sheets cut to the outlines illustrated in Figure 2. The absorbent material forming the bib and tab can be bonded to the upper plastic layer by heat process or by gluing.

The inventors also contemplate deletion of the bib and tab. In this instance, the thermal blanket would still have the viewing recess, which would be defined by the continuous seam at the head end, and which would be filled with the forward portion of the base sheet.

Circulation of heated air through the blanket is enhanced by the exhaust port openings 23, which open through the upper plastic sheet, which is heat sealed to the base of the blanket. The openings 23 vent the heated inflating air out of the outermost tubes 30 and 32, away from the underside of the blanket. Because air can circulate to, and through, the blanket edges, the inflating air in the outermost tubes is hotter than if the openings were absent. This results in hotter air being delivered through the underside apertures toward the edge of the blanket. We have measured the temperature distribution within the thermal blanket for inflating air which is heated to a medium temperature range and for inflating air

which is heated to a high temperature range. The results are provided in Table I for a blanket consisting of 13 tubes. Measurements of the temperature of air exhausted through underside apertures were made on the underside of each tube on one side of the blanket. The tubes are numbered 1-6, with 1 being the tube adjacent to the center tube, and tube 6 being the outermost tube adjacent on lateral edge of the blanket. Test apertures were made in the bottom of tube 6 only for the purposes of this test. As is evident, the distribution of temperature within the erected thermal blanket is more uniform when the exhaust port openings are provided. Further, provision of the exhaust ports also increases the average temperature within the erected structure of the blanket. Clearly, the provision of exhaust port openings at the lateral edges of the blanket delivers results which one would not expect when considering the operation of our thermal blanket with no exhaust port openings.

In our first preferred embodiment, the exhaust port openings are slits in the edge seams of our blanket. These slits vary in length from 1-3/4 to 2 inches. Each edge seam is discontinuous approximately at each corner of the blanket so that inflating air is vented away from the underside of the erected blanket. This keeps the relatively "colder" air at the blanket edges from mixing with the relatively "hotter" air exhausted into the structure through the underside apertures. The result is a "flatter" temperature profile of air within the blanket than without the vents, which raises the average temperature within the erected structure and makes the temperature distribution in the structure more uniform.

Resultantly, the clinical effect of the blanket is enhanced. Heating is better controlled, and more uniform, with greater comfort to the patient.

TABLE I

TUBE NO.	MEDIUM TEMPERATURE RANGE		HIGH TEMPERATURE RANGE	
	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS
center (inlet) tube	113.3° F.	114.1° F.	121.3° F.	121.3° F.
Tube #1	109.9°	112.3°	117.3°	117.7°
Tube #2	105.3°	109.8°	113.4°	115.0°
Tube #3	103.2°	107.1°	111.0°	113.3°
Tube #4	99.9°	104.3°	101.4°	108.6°
Tube #5	97.2°	100.0°	95.7°	104.4°
Tube #6 (outermost)	85.2°	95.8°	89.6°	99.4°
Average temp. under cover	103.8°	106.7°	108.4°	112.5°

The thermal blanket of the invention is enabled to bathe a patient in the thermally-controlled inflating medium introduced into the upper side tubes by means of a plurality of apertures 62 shown in Figures 4 and 5. The apertures extend through the underside of the blanket, which includes the layers 50 and 52. The apertures 62 are made in the footprints of the tubes of the blanket upper side according to a pattern which has been determined to deliver a very uniform thermal bath. In this regard, no apertures are provided through the underside into the lateral most tubes 30 and 32, or into the center tube 34. In addition, the apertures 62 are provided through the underside to the apertured tubes in a density which varies

inversely with the proximity of the tube to the center tube 34. Thus, the hole density increases from the tube 38a through the tube 38d. Even with the exhaust port openings, the temperature of the inflating medium exhibits a drop from the center to the lateral most tubes. The varying density of the apertures 62 tends to reduce this gradient further by forcing hotter air to the edges of the blanket. Thus, the thermal bath delivered to the patient is of a generally uniform temperature. The aperture density variation also equalizes the flow of inflating medium out of the apertures. As will be evident, the inflating pressure will be greatest at the center tube 34 and will tend to diminish toward the lateral edges of the thermal blanket. Therefore, fewer apertures are required for the tubes near the center tube 34 to deliver the same amount of air as the relatively greater number of apertures in the tubes at a greater distance from the center tube 34.

The apertures comprise openings which can be of any appropriate shape. For example, we have produced blankets with elongated apertures, approximately 1/4 inch in length.

Our invention is illustrated as we intend for it to be used in a second aspect including a foot drape in Figure 7. The foot end 14 of the thermal blanket 10 is modified to provide an uninflated drape forming section 70 formed by a rearward extension of the base sheet 50/52 and a noninflatable portion of the heat-sealable plastic bonded to the base sheet. The drape forming sheet 70 has sides 72 extending parallel to and rearwardly from the outside edge of the edge seams 43, and a rear edge 74. Optionally, the drape-forming sheet 70 further includes a pair of V-shaped cuts 76 in the rear corners thereof. The V-shaped cuts 76

are formed by converging cuts 78 and 80, extending inwardly from one of the sides 72 and the rear edge 74, respectively, to a point of intersection 82. As shown in Figure 7, the drape-forming section 70 may be formed into a foot drape 90 that includes a pair of side portions 92, a rear portion 94 and an upper portion 96. The drape 90 is so formed by joining the edges 78 and 80 of the V-shaped cuts 76 to form a pair of seams 98. To form the seams 98, the V-shaped cut edges 78 and 80 may be folded about respective lines 100 and 102 that parallel the edges 78 and 80, as shown in Figure 6. The resulting respective folded surfaces 104 and 106 may then be fastened together by appropriate means such as heat sealing. Joining the surfaces 104 and 106 forms a crease 108 and transforms the two dimensional drape forming section 70 into the three dimensional drape 90.

The resultant drape 90 is non-inflatable but erectable under the force of the heated medium circulating around the patient. The drape 90 thus traps and retains heat around the patient's feet to warm the feet. As shown in Figure 7, the drape 90 also insulates the bare skin of the feet from excessive conductive heat from the inflating hose 70 in the event the hose is oriented in a position wherein it might otherwise come in contact with the feet. Patient warming and comfort is thus further enhanced.

Our invention is illustrated as we intend for it to be used in a third aspect as an inflatable lower body covering in Figures 8 and 9. This covering warms convectively by exhausting warm air onto a patient. The thermal covering in this case is similar in all respects to the covering shown in Figs. 6 and 7, except that the covering may be shortened

to cover only the pelvic area and lower extremities of the patient. Moreover, the head end of the covering may be modified to provide an open flat working area for the placement of instrumentation and to improve visualization of the care site, as shown in Fig. 9. As in the case of the thermal coverings discussed above, the covering 110 of Figures 8 and 9 includes a head end 112, a foot end 114, a pair of lateral edges 115, and an inflation inlet cuff 116 to which may be connected through a heater tube 20 to a heater/blower assembly such as the assembly 18 shown in Figure 1. As shown in Figure 9, the covering 110 may be inflated to form a Quonset hut-like structure with a quilted upper surface 121. Like the thermal covering 10, a pattern of apertures on the undersurface of the blanket 110 convectively delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

Alternatively, the head end of the quilted upper surface 121 could extend directly from one edge 115 to the other edge 115 without the provision of a non-inflated blanket recess 122, as shown in Fig. 8. Further, an adhesive strip 124 made of an adhesive material may be attached to the head end 112 of the covering 110 and extend between the edges 115. As shown in Fig. 8a, the adhesive strip 124 is mounted with its adhesive side oriented toward the base sheet, which includes an underside layer 150 formed from a flexible material capable of bonding to a layer 152 of heat sealable plastic. The layers 150/152 are formed in the same manner as the layers 50/52 shown in Fig. 3 and described above. Mounted to the underside of the adhesive strip 124 is a backing strip 125, which may be

positioned partially between the adhesive strip 124 and the layer 152 to prevent inadvertent peel-off.

As shown in Figure 9, the adhesive strip 124 may be adhered above the patient's pelvic and groin area to prevent the migration of air from inside the covering 110 to the care site. Moreover, the optional non-inflated recess 122 may be large and well-defined in order to improve visualization of the operating field and provide sufficient working area for resting instruments or other items during the rendering of care to a patient 126.

Like its counterpart covering 10, the covering 110 includes a parallel array of elongated tubes of which 130 and 132 are the lateralmost tubes, 134 is the center tube, and the tubes 138 are arrayed between one of the lateralmost tubes and the center tube. The thermal covering 110 further includes a non-inflated yet erectable foot drape for retaining a thermal medium around a patient's feet. As in the covering shown in Figure 6, the covering 110 is provided with a non-inflated drape forming section 170 extending rearwardly from the foot end 114. The covering 170 includes a pair of sides 172 and a rear edge 174. Moreover, the drape forming sheet 170 includes a pair of V-shaped cuts 176 in the rear corner thereof. As shown in Figure 9, the drape forming section 170 may be formed into an erectable foot drape 190 that includes a pair of side portions 192, a rear portion 194, and an upper portion 196. As in the covering 10, the drape 190 of the covering 110 is formed by joining the edges of the V-shaped cuts 176 to form a pair of seams 198.

As with the longer full-body thermal blanket of Figs. 1 and 2, the covering 110 may be provided without a foot

draped as appropriate. In that case, it may be desirable to slideably mount a protective sleeve 200 over the heater tube 20 to prevent the tube from contacting the patient.

Advantageously, it will be observed that the lower body warming cover 110 maintains a thermal medium around the pelvic and groin area and lower extremities of the patient, while at the same time exposing the patient's torso and head as may be necessary for the provision of medical care and treatment to those areas.

Alternatively, or in combination with the lower body thermal covering 110, an upper body thermal covering 210 could be provided as shown in Figures 10 and 11. The upper body thermal covering 210 is structurally and functionally similar in most respects to the thermal coverings 10 and 110 discussed above. Thus, the thermal covering 210 includes a head end 212, a foot end 214, a pair of lateral edges 215, and an inflation inlet cuff 216 which may be connected through a heater tube 20 to an external heater/blower assembly such as the assembly 18 shown in Figure 1. The thermal covering 210 further includes a quilted upper surface 22, which may have non-inflated recess 222 located at the foot end of the covering, as shown in Fig. 11. Thus, with the upper torso and arms of the patient being thermally bathed, the uninflated recess 222 permits observation of the patient's middle torso from almost any location with respect to the thermal covering 210.

Alternatively, as shown in Fig. 10, the quilted upper surface 221 could extend across the entire expanse of the covering between the edges 215 such that no uninflated recess 222 is formed. It is preferable in most cases,

however, to provide a recess 223 in the quilted upper surface 221 and the foot end 214 of the covering 210 to accommodate the curvature of the patient's torso, as shown in Fig. 11.

There may be additionally provided an adhesive strip 224 mounted to the foot end 214 of the covering 210. As shown in Fig. 10a, the adhesive strip 224 is mounted with the adhesive side facing the base sheet, which includes an underside layer 250 formed from a flexible material capable of bonding to a layer 252 of heat sealable plastic. The layers 250/252 are formed in the same manner as the layers 50/52 shown in Fig. 3 and described above. Mounted to the underside of the adhesive strip 224 is a backing strip 225, which may be positioned partially between the adhesive strip 224 and the layer 252 to prevent inadvertent peel-off. As shown in Fig. 11, the adhesive strip 224 may be adhered to the patient's torso to prevent the migration of air toward the care site.

The covering 210 further includes an array of elongated tubes of which 230 and 232 are the lateral most tubes, 234 is the center tube and the tubes 238 are arrayed between one of the lateral most tubes and center tube. In addition, the thermal covering 210 includes a cutout area 240 centrally positioned at the head end 212 of the covering. The cutout 240 is formed by truncating the lateralmost tube 230 and an adjacent tube 238. The recess 240 permits observation of the patient's head and neck from almost any location with respect to the thermal blanket 210. It also assists in thermally covering the patient's shoulders and arms without covering the patient's face. As shown in Figures 10 and 11, the bottom layer 250/252 of the

covering 210 may extend slightly beyond lateral edges 215 or the head end 212, or it may be coextensive therewith.

As shown in Figure 11, the thermal covering 210 is positioned over the patient's upper torso and arms so as to thermally control those areas while leaving the patient's lower torso exposed for the provision of care. As indicated, the thermal covering 210 may be used alone or in combination with the thermal covering 110 depending on the location of the care site. Thus, various selected portions of the patient may be selectively warmed with the illustrated thermal coverings while care and treatment may be rendered to other areas. In addition, a plastic head drape 260 may be adhesively mounted to the covering 210 over the patient's chest, and adjacent the head end 230. The plastic head drape 260 is placed over the patient's head and one or more vents 270 may be provided to direct warmed air to the head area.

In a preferred method of operation, one or both of the coverings 110 and 210 may be selectively employed on a patient to warm selected portions of the patient while permitting other portions to remain exposed for treatment. In utilizing the coverings 110 and 210, either alone or in combination, the covering 110 or 210 is first placed over the patient. The adhesive backing 125 or 225 is removed from the adhesive strip 124 or 224 and the adhesive strip is adhered to the patient to prevent the migration of air toward the care site. The hose 20 is then attached to the covering, an appropriate temperature is selected on the heater unit 18 and the unit 18 is activated. For the covering 110, the protective heater tube 200 cover may also be used when the cover does not include a foot drape. For

the covering 210, the head drape 260 may be adhered to the quilted portion 221 over the patient's chest and draped over the patient's head. As a final measure, a conventional blanket may be placed over the covering 110 or 210. During operation, the patient's temperature should be monitored regularly and the air temperature setting of the heater unit 18 adjusted accordingly.

Many modifications and variations of our invention will be evident to those skilled in the art. For example, thermal coverings for additional selected patient areas could be implemented depending on the location of the care site and the need for thermally maintaining other areas. It is understood that such variations may deviate from specific teachings of this description without departing from the essence of the invention, which is expressed in the following claims.

We claim:

CLAIMS

1. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers;

a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet; and

said thermal blanket being sized to extend from a patient's pelvic and groin area to the patient's feet.

2. The improvement of claim 1 further including a non-inflatable foot drape.

3. The improvement of claim 1 further including an adhesive strip at said head end to adhere said head end to a patient and prevent migration of air towards a care site.

4. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers;

a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet; and

said thermal blanket being sized to extend from a patient's neck to the patient's upper torso and to cover the patient's arms and shoulders.

5. The improvement of claim 4 further including a flat uninflatable section at said foot end.

6. The improvement of claim 4 further including an adhesive strip at said foot end to adhere said foot end to a patient and prevent migration of air towards a care site.

2 7. The improvement of claim 4 further including a
head drape at said head end to drape over a patient's head
and a vent for directing heated air under said head drape.

2 8. An inflatable thermal blanket for convectively
controlling the temperature of a human body, comprising:

4 a self-erecting inflatable covering with a head
end, a foot end, two edges, and an undersurface;

6 an inflating inlet for admitting a
thermally-controlled inflating medium into said
covering;

3 an array of apertures in said undersurface for
exhausting a thermally controlled inflating medium
from said covering to said undersurface;

2 means in said inflatable covering for equalizing
the temperature of a thermally controlled inflating
medium in said inflatable covering by circulating said
inflating medium toward said two edges;

5 an uninflatable extension in said inflatable
covering at said head end; and

3 said thermal blanket being sized to extend
from a patient's pelvic and groin area to the
patient's feet.

2 9. The thermal blanket of claim 8 further including
a non-inflatable foot drape.

1 10. The thermal blanket of claim 8 further including
an adhesive strip at said head end to adhere said head end
to a patient and prevent migration of air towards a care
site.

11. An inflatable thermal blanket for convectively controlling the temperature of a human body, comprising:

a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface;

an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end; and

said blanket being sized to extend from a patient's neck to the patient's upper torso and to cover the patient's arms and shoulders.

12. The thermal blanket of claim 11 further including a flat uninflatable section of said foot end.

13. The improvement of claim 11 further including an adhesive strip at said foot end to adhere said foot end to a patient and prevent migration of air towards a care site.

14. The improvement of claim 11 further including a head drape at said head end to drape over a patient's head and a vent for directing heated air under said head drape.

15. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

a continuous seam between said overlaying material sheet and said base sheet near said head end which closes ends of said inflatable chambers;

a non-inflatable section of said thermal blanket extending substantially between said continuous seam and said head end and including an end portion of said flexible sheet; and

a flexible heater hose attached to said thermal blanket to provide heated air to said inflatable chambers, said flexible heater hose including a protective sleeve slideably disposed thereon to prevent hose contact with a patient.

16. An inflatable thermal blanket for convectively controlling the temperature of a human body, comprising:

a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface;

an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end; and

a flexible heater hose attached to said thermal blanket to provide heated air to said inflatable chambers, said flexible heater hose including a protective sleeve slideably disposed thereon to prevent hose contact with a patient.

17. A method for thermally warming a selected portion or portions of a patient for rendering care to other portions of the patient, comprising the steps of:

selecting one or more inflatable thermal blankets sized to cover a portion or portions of a patient to be thermally warmed so that care may be administered to other portions of the patient, said inflatable thermal blanket(s) being of a type that comprise(s):

a self-erecting inflatable covering with a head end, a foot end, two edges, and an undersurface; and

an inflating inlet for admitting a thermally-controlled inflating medium into said covering;

an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;

means in said inflatable covering for equalizing the temperature of a thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges;

an uninflatable extension in said inflatable covering at said head end or said foot end; and

an adhesive strip at said head end or said foot end having an adhesive portion facing in the direction of said thermal blanket undersurface and a removable backing covering said adhesive portion;

said method further comprising the steps of:

placing the thermal blanket(s) over the portion(s) of the patient to be thermally warmed such that the adhesive portion of said blanket(s) is oriented toward a care site;

removing the backing from said adhesive portion and adhering the adhesive to the patient to prevent the migration of air towards a care site;

attaching a heating tube or tubes from a heating unit to said thermal blanket(s);

selecting an appropriate temperature and activating the heating unit; and

monitoring the patient's temperature regularly and adjusting the heating unit temperature as required by the patient's temperature.

18. The method of claim 17 wherein the area(s) of a
2 patient to be covered include(s) the area extending from
the patient's pelvic and groin area to the patient's feet.

19. The method of claim 18 wherein said thermal
2 blanket extends from the patient's pelvic and groin area to
the patient's feet and wherein the adhesive portion of said
4 thermal blanket is adhered to the patient above the
patient's pelvic and groin area.

20. The method of claim 19 further including the step
2 of placing a protective sleeve over the heater tube
adjacent said thermal blanket to prevent the heater tube
4 from contacting the patient.

21. The method of claim 17 wherein the area(s) of a
1 patient to be covered include(s) the area extending from
the patient's neck area to the patient's chest and
including the patient's arms.

22. The method of claim 21 wherein said thermal
blanket extends from the patient's neck area to the
patient's chest and also covers the patient's arms and
wherein the adhesive portion of said thermal blanket is
adhered to the patient's chest.

23. The method of claim 22 further including the step
of adhering a head drape on or near said head end of said
thermal blanket and draping the head drape loosely over the
patient's head.

24. The method of claim 17 further including the step of draping a conventional blanket or blankets over said thermal blanket(s).

25. A thermal care system for thermally warming a patient comprising:

- an inflatable thermal blanket having at least one inflatable chamber therein and an air inlet for admitting air to said chamber;

- a heater/blower assembly providing a source of heated air;

- a heater tube extending from said heater/blower assembly to said thermal blanket air inlet; and

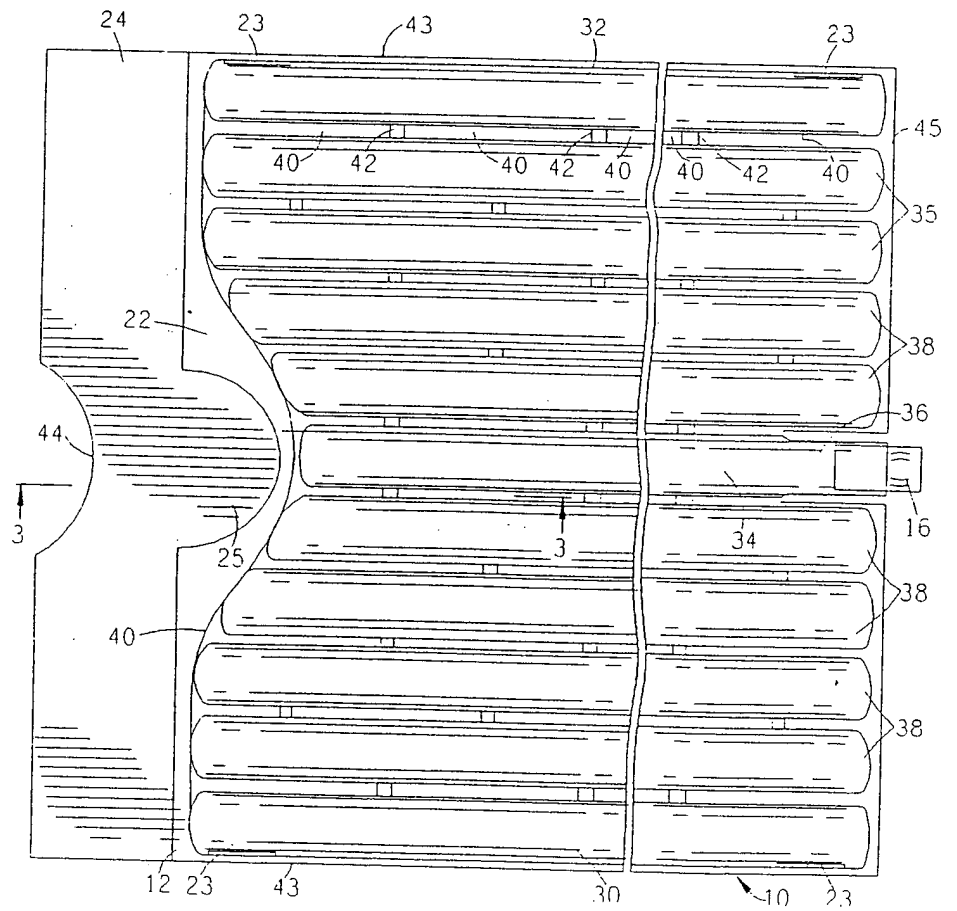
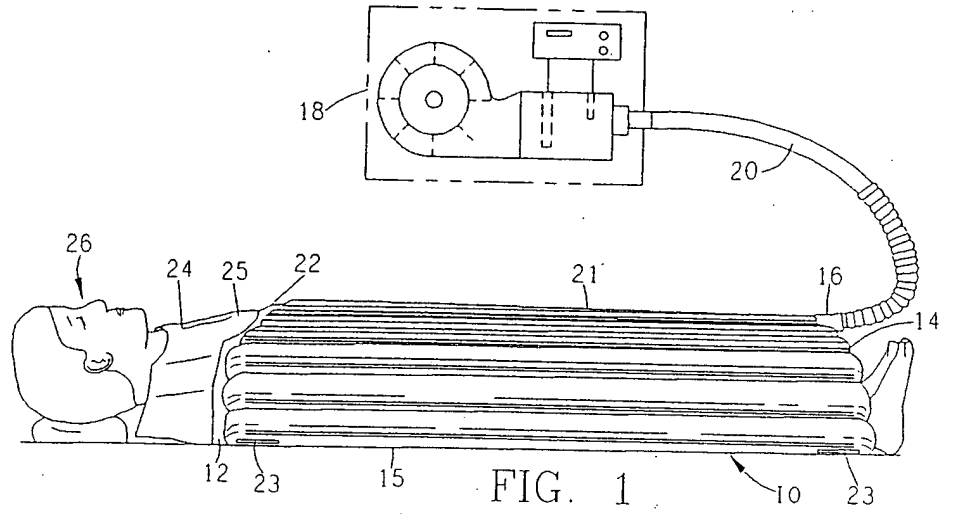
- a protective sleeve slideably disposed over said heater tube adjacent said thermal blanket air inlet to prevent said heater tube from contacting the patient.

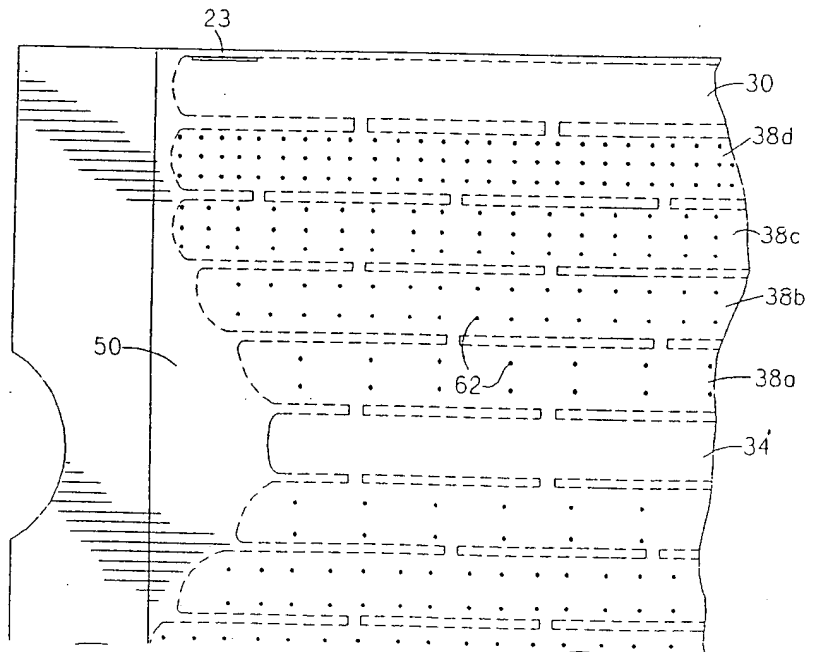
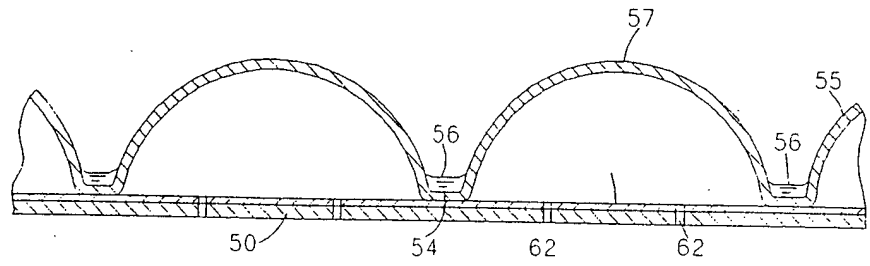
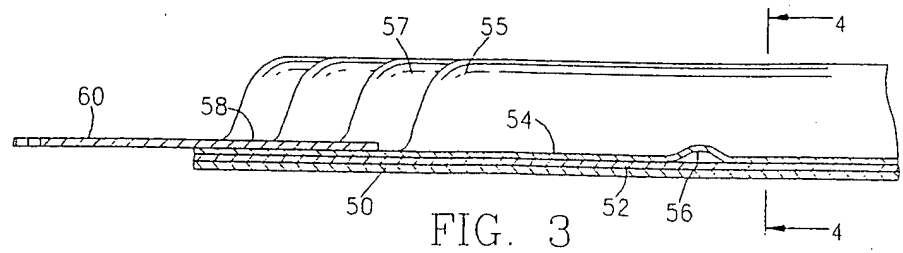
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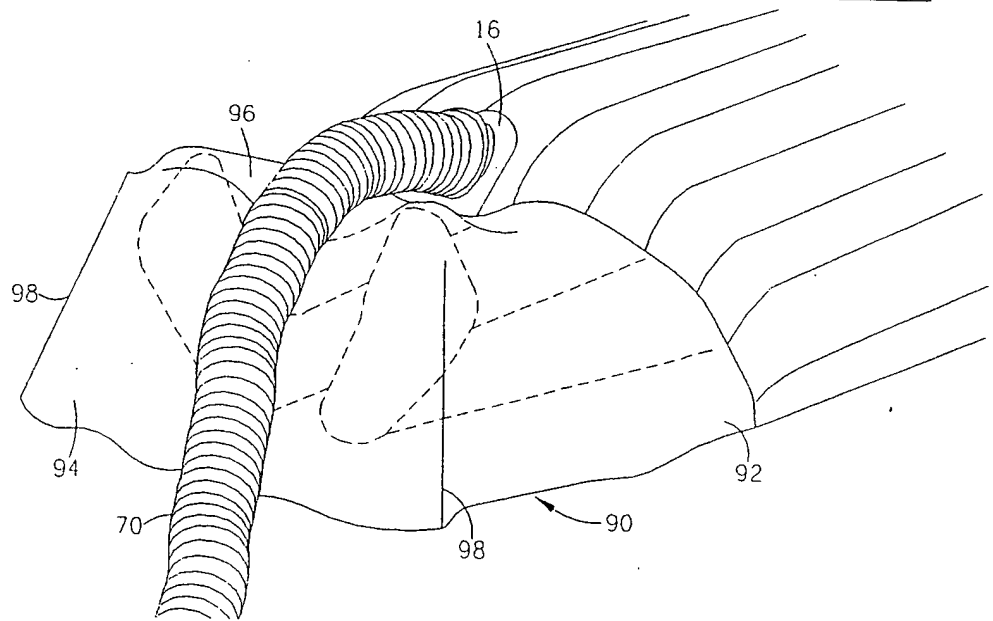
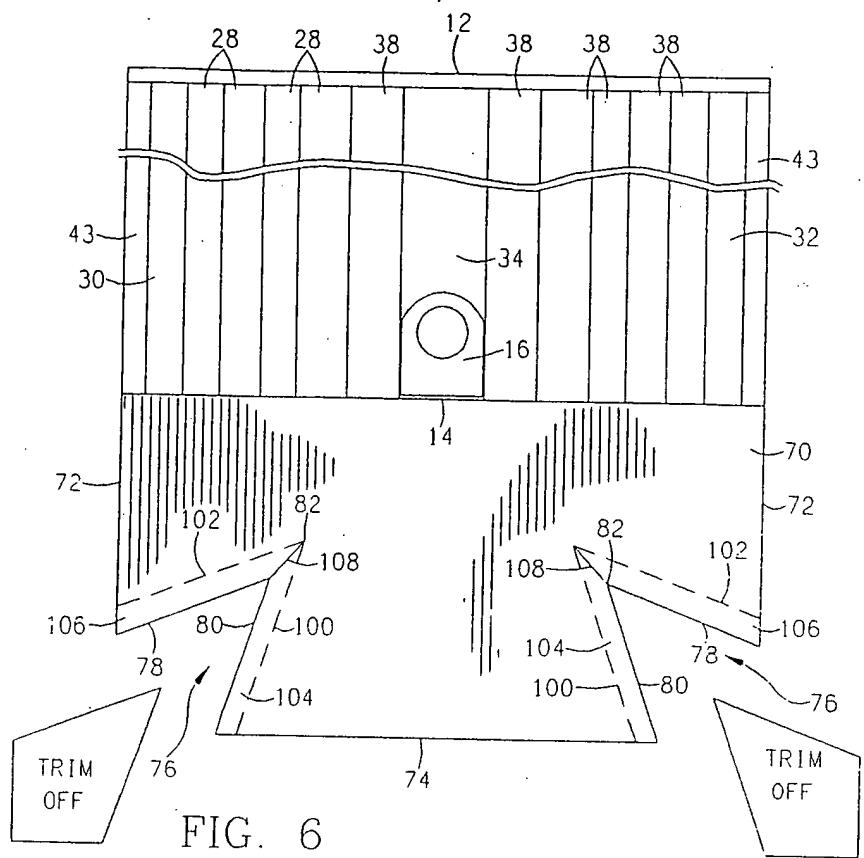
ABSTRACT

A thermal blanket includes an inflatable covering with a head end, a foot end, two edges and an undersurface. The covering is inflated through an inlet at the foot end by a thermally-controlled inflating medium. An aperture array on the undersurface of the covering exhausts the thermally controlled inflating medium from the covering. Exhaust port openings are provided that the edges of the covering to vent the inflating medium, which enhances circulation of the thermally-controlled medium through the cover. An uninflatable section is provided at the head end, together with an absorbent bib attached to the covering, adjacent the uninflatable section. An uninflatable section may also be provided at the foot end having a pair of seams to form an erectable drape section. When inflated, the thermal blanket self-erects and provides a bath of thermally-controlled inflating medium to the interior of the erected structure. The enhanced circulation of the medium through the covers maintains a relatively high average temperature under the blanket and a relatively uniform distribution of temperature in the inflating medium which is exhausted through the apertures into the structure's interior. When the structure covers a patient, the uninflatable section at the head end provides a relatively unobstructed view of the patient's face, while the absorbent bib maintains a relatively sanitary environment in the area beneath the patient's head. The uninflatable section at the foot end retains heat from the

inflating medium to warm the patient's feet and insulate the bare skin of the feet from excessive conductive heat from the hose connected to the inflation inlet. The thermal blanket may be sized to cover selected areas of a patient such as the upper body, including the chest, arms, or shoulders, or the lower body, including the pelvic and groin area and the legs.







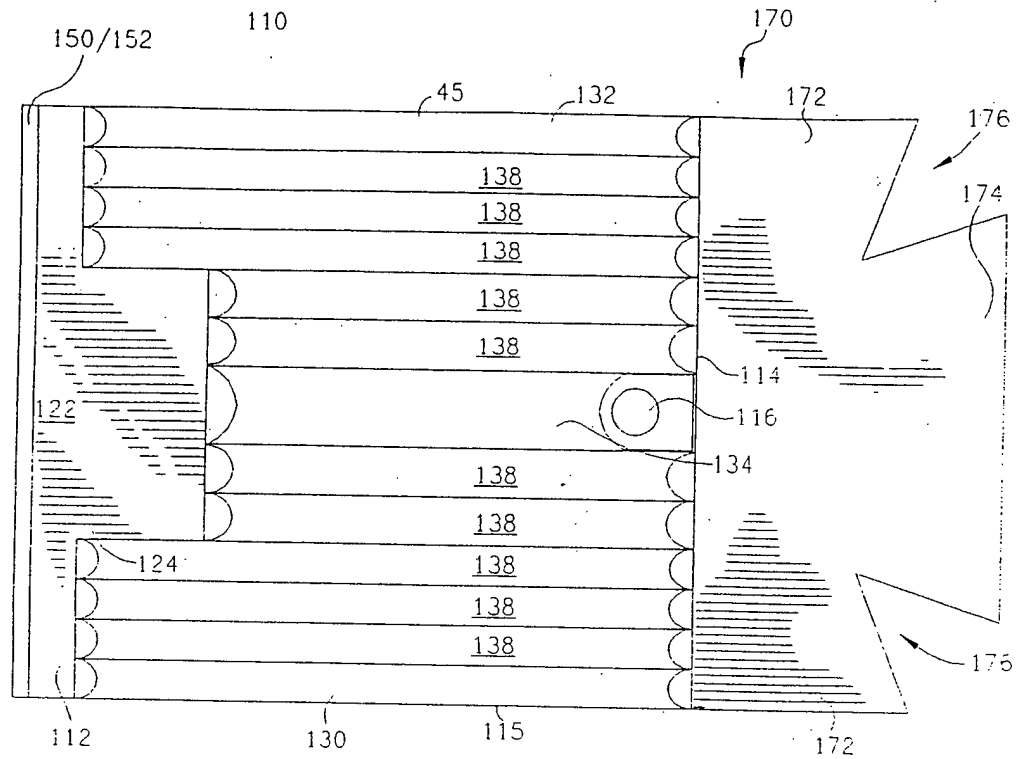


FIG. 8

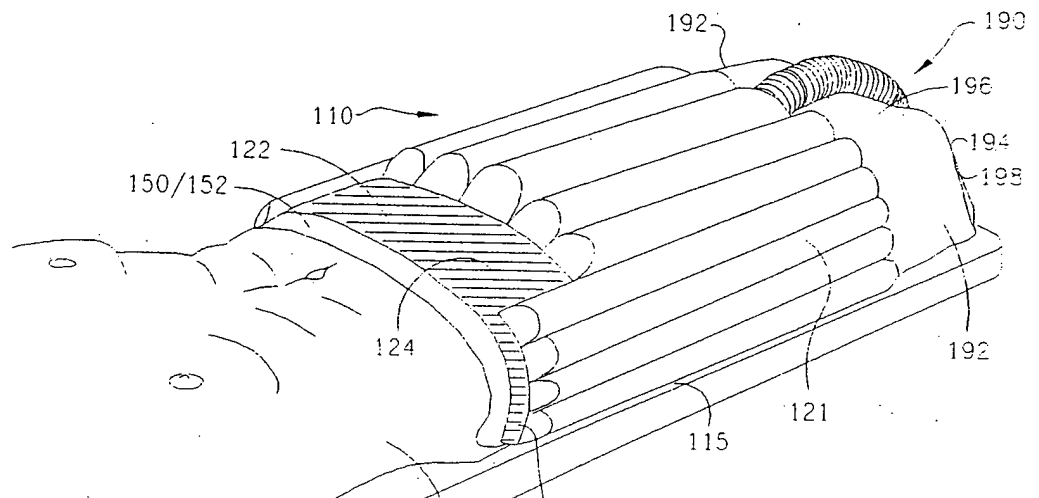
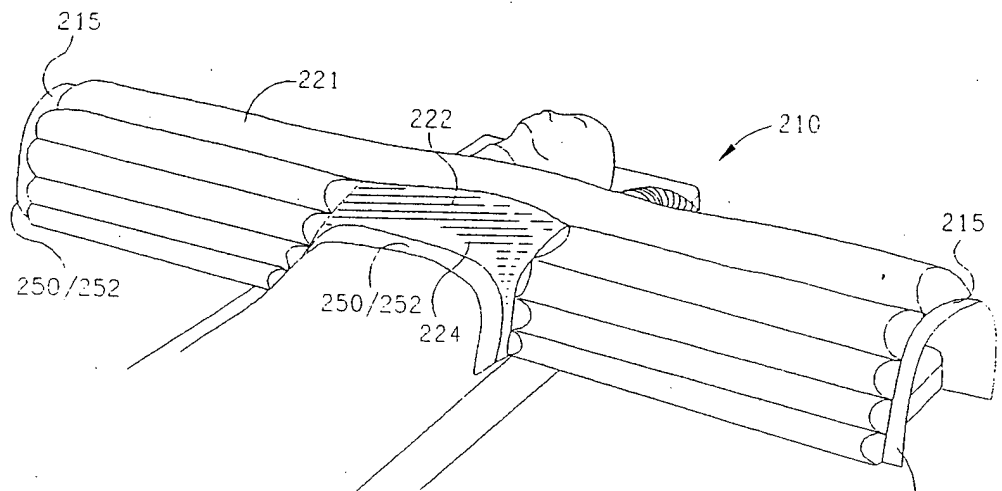
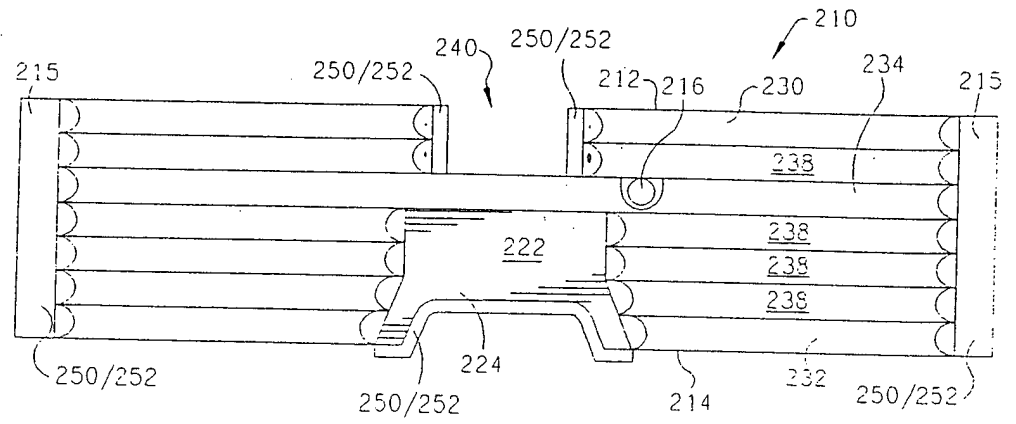


FIG. 10



As a below named inventor, I hereby declare that:

my residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:
THERMAL BLANKET

the specification of which

X is attached hereto

was filed on _____, as Application Serial No. _____,
and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified Specification, including the Claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37 CFR 1.56(a).

I hereby claim foreign priority benefits under Title 35 USC 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Priority Claimed

(Number)	(Country)	(Day/Month/Year Filed)	(Yes)	(No)
(Number)	(Country)	(Day/Month/Year Filed)	(Yes)	(No)

I hereby claim the benefit under Title 35 USC 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35 USC 112, I acknowledge the duty to disclose material information as defined in Title 37 CFR 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

(App. Serial No.) (Filing Date) (Status, i.e. patented, pending, abandoned)

(App. Serial No.) (Filing Date) (Status, i.e. patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected therewith: Freling E. Baker, Reg. #24,078; Lawrence A. Maxham, Reg. # 24,483; Michael H. Jester, Reg. #28,022; Terrance A. Meador, Reg. #30,298; and Walter W. Duft, Reg. #31,948. Address all telephone calls to Walter W. Duft at Telephone No. (619) 233-9004 and address all correspondence to Walter W. Duft; BAKER, MAXHAM, JESTER & MEADOR, 110 West "C" Street, Suite 1202, San Diego, California, 92101.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF SOLE OR FIRST INVENTOR

INVENTOR'S SIGNATURE

DATE

Scott D. Augustine

Scott D. Augustine

X 1/7/91

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Page 2/Declaration/Power of Attorney

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FULL NAME OF FOURTH JOINT INVENTOR IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP

POST OFFICE ADDRESS

FULL NAME OF FIFTH JOINT INVENTOR IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE		CITIZENSHIP

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S. GOLDSCHMIDT.
Surgical-Bandage.

No. 222,690.

Patented Dec. 16, 1879.

Fig. 1.

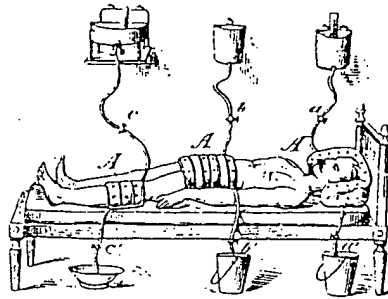


Fig. 2.

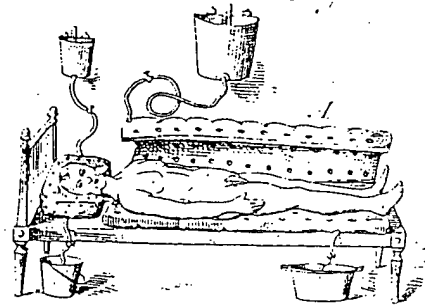


Fig. 3.

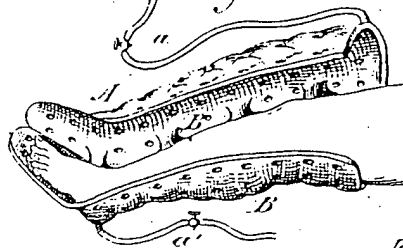


Fig. 4.

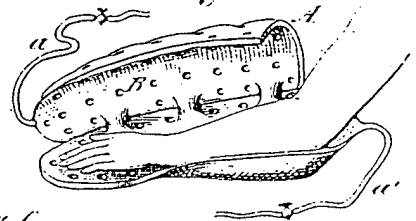


Fig. 5.

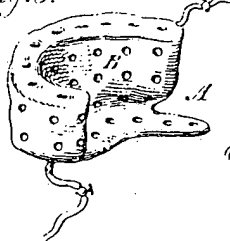


Fig. 6.

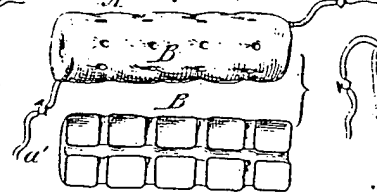


Fig. 7.

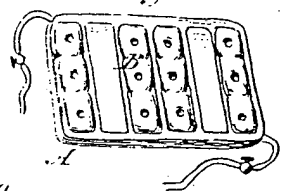


Fig. 8.

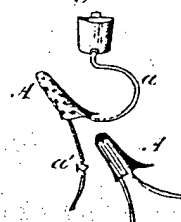
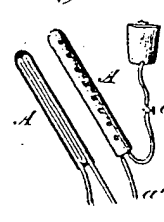


Fig. 9.



WITNESSES:

Carl Karp
Otto Busch

INVENTOR:

Samuel Goldschmidt
BY *Paul Goepel*
ATTORNEY.

UNITED STATES PATENT OFFICE.

SAMUEL GOLDSCHMIDT, OF BERLIN, PRUSSIA, GERMAN EMPIRE.

IMPROVEMENT IN SURGICAL BANDAGES.

Specification forming part of Letters Patent No. 222,699, dated December 16, 1879; application filed July 21, 1872.

To all whom it may concern:

Be it known that I, SAMUEL GOLDSCHMIDT, of Berlin, Prussia, German Empire, have invented an Improved Surgical Bandage, (cataplasm,) of which the following is a specification.

In the accompanying drawings, Figures 1 and 2 represent perspective views of my improved surgical bandage, shown as applied, respectively, to a part of and to the entire body. Figs. 3, 4, 5, 6, 7, 8, and 9 are detail views of the bandage, shown as adapted to be applied, respectively, to the leg, arm, abdomen, head, vagina, rectum, or other part of the body.

Similar letters of reference indicate corresponding parts.

This invention relates to improved ventilating bandages for cooling or heating any part of or the entire body in a clean, uniform, and reliable manner; and the invention consists of bandages of water-proof material having ventilating openings or passages.

In the drawings, A represents my improved bandage, which is made in the shape of a cushion of elastic and water-proof material, and of any desired shape, large or small, so as to be adapted for any part of or for the entire body. The bandage is of greater or less thickness, and provided either with tubes or openings B, according to the thickness of the bandage. These tubes or openings pass transversely through the bandage, and admit the passage of the air to the inside of the same. One end of the bandage is connected by a tube, a, b, or c, with an elevated supply-reservoir containing warm or cold water, the temperature of which is regulated by means of ice for cold applications, or by a spirit-lamp and thermometer for warm cataplasm. At the lower end or part the water is conducted off by a discharge-tube, a', b', or c', which leads to a suitable vessel. Both the inlet and outlet tubes are provided with stop-cocks for properly regulating the circulation of water.

The transverse ventilating tubes or open-

ings B have not only the advantage of admitting atmospheric air, but also of admitting the escape of vapor, &c. They further effect a better distribution of the water, so that a more uniform temperature throughout the entire bandage is obtained. The openings also admit the application of cooling, disinfecting, or other medicaments, such as carbolic acid, &c., without being obliged to take off the bandage.

My improved ventilating-bandages have the following advantages: First, the bandage can remain permanently in position, and need not be changed, so as to annoy the patient; second, the temperature of the bandage can be accurately regulated; third, the bandage incloses entire parts, and fits snugly and comfortably thereto; fourth, full ventilation by access of air and escape of vapors is obtained; fifth, the bandage exerts no pressure, owing to its reduced size; sixth, it forms in many cases an effective and convenient substitute for the permanent baths applied to the entire body or parts thereof.

I am aware that bandages formed of double walls, between which a cooling or heating medium passes, are well known, and I do not claim the same, broadly.

Having thus described my invention, I claim as new and desire to secure by Letters Patent—

A surgical bandage formed of double walls of water-proof material, said walls being connected by a number of transverse passages, which provide openings for the access of air to the skin, and around which the liquid circulates, substantially as and for the purpose set forth.

In testimony whereof I have signed my name to this specification in the presence of two subscribing witnesses.

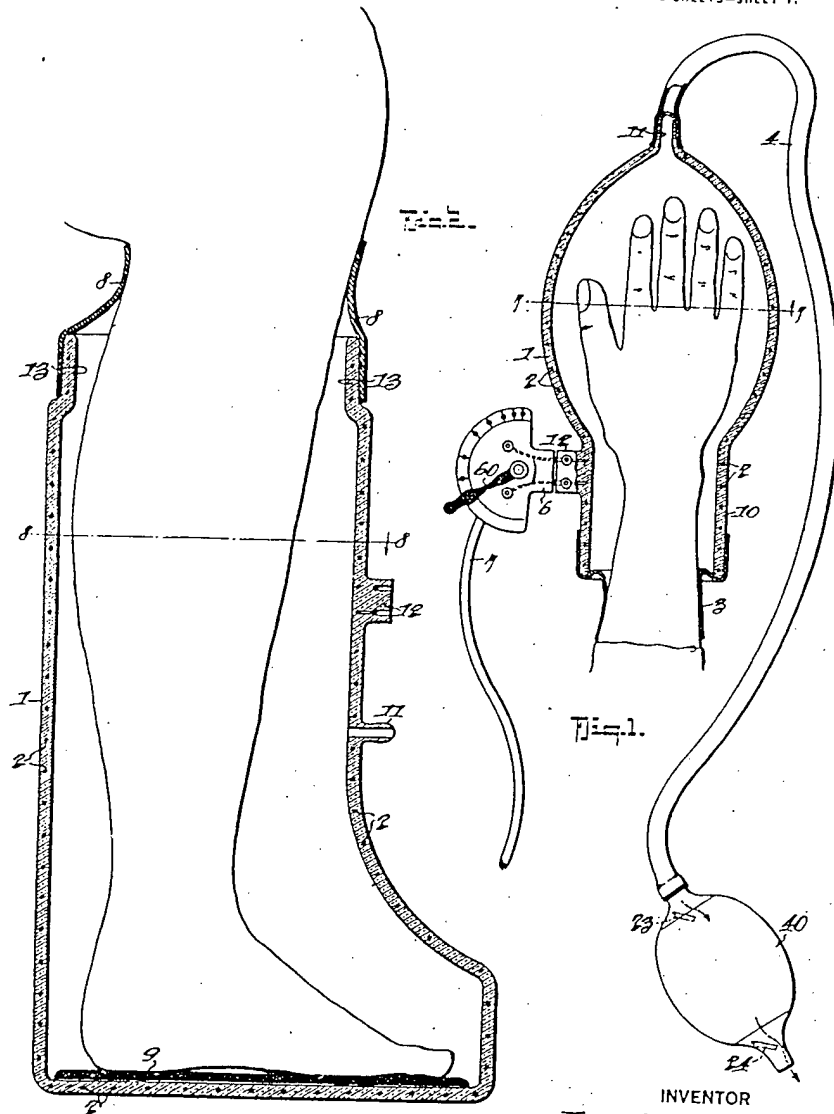
SAMUEL GOLDSCHMIDT.

Witnesses:

H. KREISMAN,
EDWARD P. MACLEAN.

1,399,095.

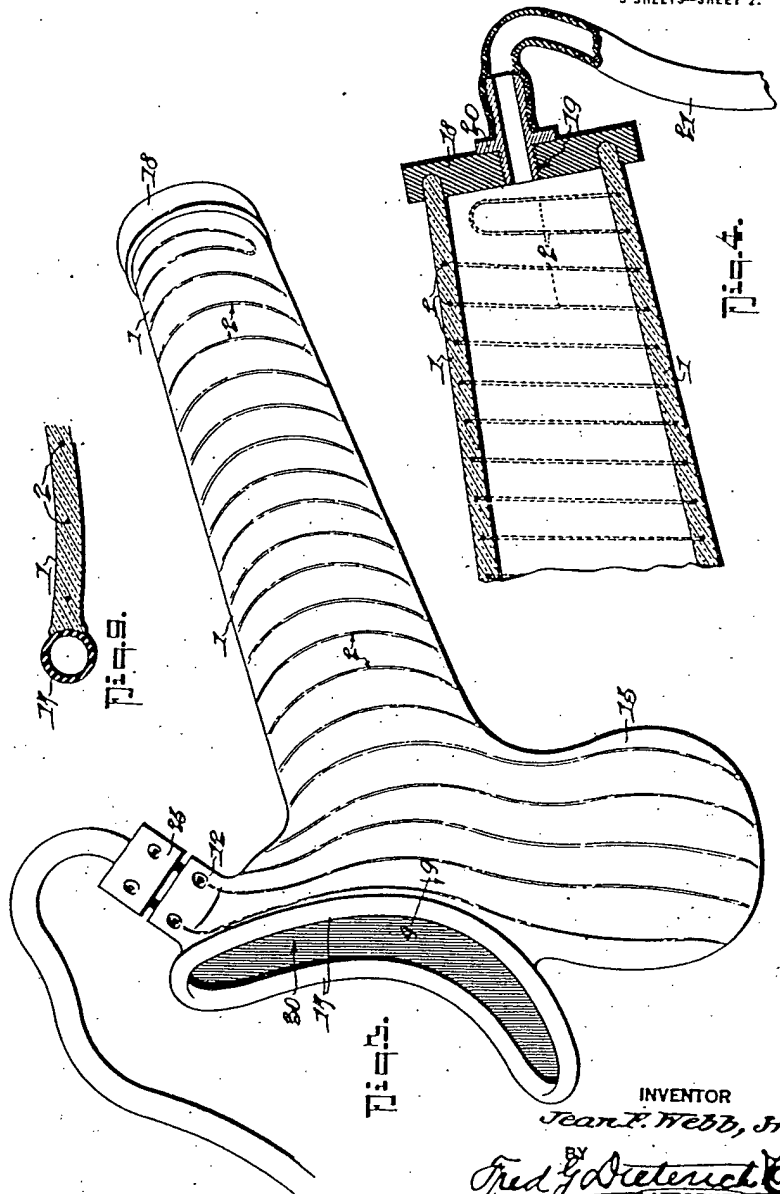
Patented Dec. 6, 1921.
3 SHEETS—SHEET 1.



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Patented Dec. 6, 1921.
3 SHEETS—SHEET 2.



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[illegible]

istic of my invention is maintained and they comprise essentially a bulbular body having the electric heating coils 2 embedded therein, for generating the heat, a switch connection, preferably attached to the body, and a connection on the body for the attachment thereof of an air or vacuum creating bulb, and when the member or part being treated is to be entirely incased, suitable means is attached to the body for making an air tight closure at the open end of the body.

As shown in Fig. 1, the body 1 is of a bulbular shape and of a size suitable for receiving therein the hand and the wrist of the user, it being understood that the said body 1, may be long enough to extend to near the elbow, to adapt it for the ready treatment of a sprained wrist or forearm.

At the open end, the body 1, shown in Fig. 1, is restricted and it there terminates in a tubular extension 10 which provides for the convenient attachment thereto of a broad sheet rubber band 3 that aids in keeping the attachment in the desired operative position and also effects an air tight closure for the hollow body.

In the form referred to, the body 1 at the outermost end has a tubular nipple or extension 11, for receiving the end of a flexible hose 4 of an ordinary vacuum bulb device 40, which, when manipulated in the usual way, draws the air from and creates a vacuum within the said body 1.

At a suitable point, preferably at the straight neck, the body 1 is formed with a coupling block 12, designed for receiving the ordinary type of plug switch 6 and which may have the usual regulating lever 60 for controlling the strength of the current that passes through the heat coils 2.

It should be stated that in practice, the wire cord 7 is supplied with the usual form of switch plug for connecting with the house electric light fixtures or to a battery.

In Fig. 2 is shown substantially the same form of appliance illustrated by Fig. 1, except that the hollow body is shaped for receiving the leg or foot, and the nipple 11 for attaching the vacuum creating bulb device is located below and adjacent the coupling block 12.

In this latter form, a rubber closure band 8 is also used and it engages the neck portion 13 of the body and the leg to make the air tight closure for the upper end.

While the form shown in Fig. 2 is especially adapted for receiving the foot and the leg below the knee, it is obvious the body 1 may be of sufficient length to include the knee joint, and in this latter form, an asbestos plate 9 is located on the bottom of the body 1 to avoid burning the foot.

The form shown in Fig. 2 is especially well adapted for the treatment of gout, varicose veins in the leg and sprained ankles

and, when made long enough, for the treatment of rheumatic and other diseases of the knee.

Vacuum tubes for the male organ alone have long been known or used, but they did not inclose the orches (testicles), the seat of the varicocele; and consequently they could not furnish the proper treatment needed to relieve congested or abnormal conditions in all the parts.

Fig. 5 illustrates a further form of my improved appliance that is particularly designed for use for effecting the proper treatment of those parts last referred to and, in the said form, the body 1 includes, in addition to the bulbular body portion 1, a sack-like member 15 for receiving the orches, and a vacuum cup-like open end 30, the cup-like open end being shaped to conform to the contour of the pelvis and the thighs, and to provide an air tight closure, as the appliance is pressed tightly against the body, the said cup-like edge has a flange on which is received a rubber gasket 17 cemented or otherwise made fast to the said edge.

In this latter form of my appliance, the outer end of the glass body 1 which is in the nature of a tube, is closed by a disk 18 (preferably hard rubber) provided with an internally threaded aperture 19, for receiving the threaded coupling 20 on the end of the flexible tube 21 that joins with the air exhasting rubber bulb 40 provided with the usual valve devices 23-24 in the opposite ends thereof, as shown.

Near the inner end, the body 1 has the switch portion for connection with the switch plug 25 on the end of the electric conduit cord that joins with the source of electric supply.

In Fig. 6 is shown a still further modification of my invention, the said form being especially designed for cupping on the local applications to any part of the human body, and in the said form, the body 1 is also provided with a rubber covered edge or rim to provide for an air tight closure as the appliance is held pressed against the part of the human body to be treated.

In the latter construction, the body 1 is bowl-shaped and has its crown or inner end secured air tight in any suitable manner, to a head portion 35 that constitutes a block for receiving the circuit closing member 36 to which the current wire lead 37 connects. 38 designates a central switch in the cord or lead 37 for coupling with the source of electrical energy.

Block 35 has an aperture that opens into the bowl-shaped body and with which connects the stem of a vacuum bulb 31 and it also has a socket 32 for receiving a hard rubber handle 33.

From the foregoing description taken in connection with the drawings, the complete

construction of, the manner in which the appliances may be used and the advantages thereof will be especially apparent to those familiar with the use of appliances of the character stated.

Among many other advantages of my invention, it should be mentioned that the same may be readily shaped in various forms suitable for the treatment of different parts, or members, of the human body and capable of being readily adapted for use by connecting the appliance with a house service electric plug or battery.

The patient can easily apply the appliance and maintain it at the desired positions for the special treatment desired, and by reason of having the switch connections and the vacuum devices combined with the appliance as shown and described, the user can apply the heat treatment or the vacuum treatment either alternately or together and by observation, he can regulate either curative agent as conditions may make desirable for effecting a speedy and effective cure.

While I have illustrated a number of forms of my invention, to illustrate the adaptability of the same for the treatment of various parts of the body, it is understood appliances either larger or smaller sizes for the treatment of the full length of leg, individual fingers, elbows or other joints may be readily made without in the least departing

from the generic form of my invention as comes within the scope of the appended claims.

What I claim is:

1. A vacuo-thermic appliance comprising a container of transparent heat resisting material, electric circulation wires embodied in the entire outside transparent shell of the said container, a circuit closure connected with the said container, the latter being provided with an open end adapted for being secured air tight against the human body, a source of electrical energy connected with the circuit closure and means attached to the container for effecting vacuum within the container, as desired.

2. As a new article, a vacuo-thermic medical appliance that comprises a container open at one end into which may be received a part of the human body to be treated, heat coils embedded in the shell of the container, a block that constitutes a closure for the other end of the container and into which the terminals of the heat coils extend, a circuit closure in connection with the said terminals, the said block having an air passage in communication with the interior of the container and a vacuum creating bulb attached to the said block and in communication with the air passage therethrough.

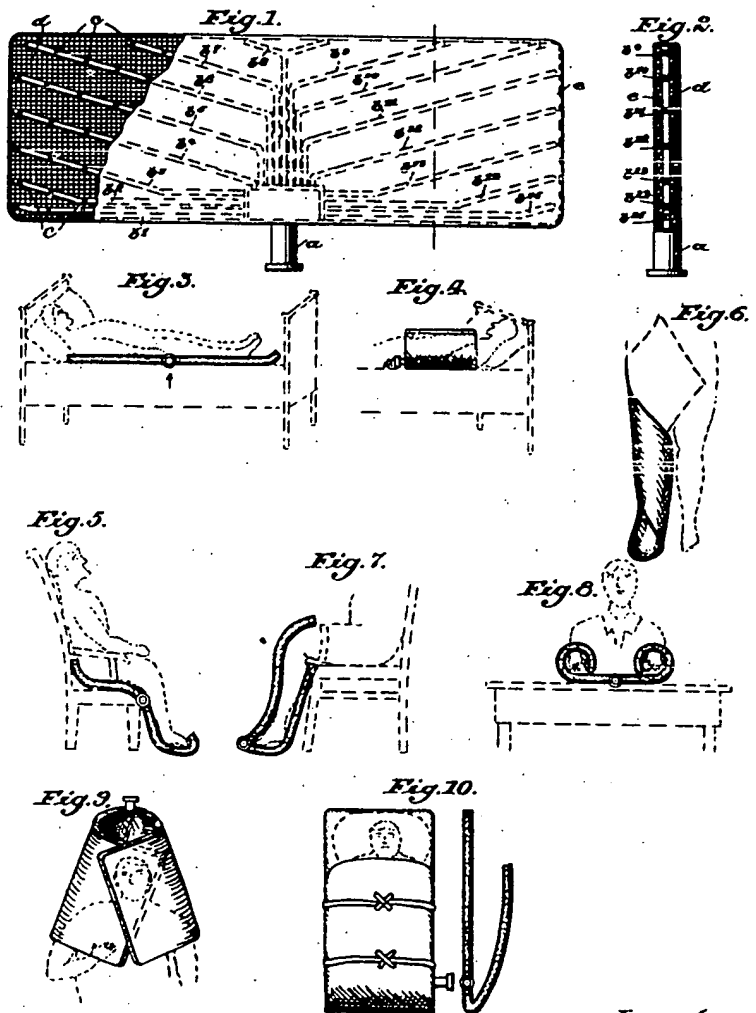
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Oct. 7, 1930.

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HOT AIR MAT

1,777,982

Filed June 10, 1929



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UNITED STATES PATENT OFFICE

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HOT-AIR MAT

Application filed June 10, 1929, Serial No. 909,749, and in Germany February 20, 1929.

This invention relates to a hot air mat for use in the treatment of disease and also for other purposes.

The present invention seeks to remove the disadvantages of the prior art and is based, whilst avoiding any rigid frame, on the idea of placing the tube system, which was hitherto rigid and fixed to the mat, in the mat itself, in such a manner that, instead of the rigid tube according to known art referred to above, flexible metallic tubes are used and are permanently fixed inside the mat, so that their position cannot vary.

The system of tubes is fan-shaped which, in no way, hinders the rolling up or adaptability of the mat, but imparts, in the manner of the bones of a fish, and in spite of maintaining the flexibility, such a degree of permanence in shape and protection against compression, that resistance is offered to any possible outside influence.

Thus the whole of the drawbacks enumerated above are eliminated. The patient can be wrapped in the new mat as quickly and as easily as in an ordinary quilt, and also a thorough and uniform distribution of hot air is ensured, as the distance between the top and underside of the mat is maintained constant by the flexible metal pipes themselves, thereby ensuring the passage of air under all circumstances.

The metallic tubes, according to the present invention are embedded in a wire netting, whereby any heat which may naturally become stored up in the walls of the tubes is uniformly distributed and simultaneously, the certain degree of stiffness of the wire netting which exists in spite of the flexibility, prevents any sagging of the covering layer of the mattress or mat which might endanger the distribution of the air. The relatively stiff wire netting takes up uniformly the pressure of the patient's body so that the patient is not troubled by localized pressure of the fish-bone-like embedded tubing.

The present invention, however, makes use of ordinary flexible metallic tubing, in the practically rigid walls of which separate holes are provided. In this way a strictly

controllable air distribution is obtained and, if necessary, by varying the distance between the holes the distribution can always be effected perfectly.

In the drawing is shown diagrammatically an embodiment of the invention.

Fig. 1 is a plan view of the improved mat, with the upper layers partly removed.

Fig. 2 is a side elevation of Fig. 1 partly in section.

Figs. 3-10 show various methods of using the mat.

The air, heated in any desired manner, enters a pipe *a*, and is thence distributed, for example into fifteen metallic tubes *b*¹-*b*¹⁵ (first distribution), and then passes through specially distributed holes *c* in the tubes (second distribution) into a hollow space formed by wire netting *d* and a removable, washable fabric covering *e*, and in which space an additional exchange of pressures, air and heat takes place, whereupon the hot air passes out through the fabric covering in extremely fine and uniform distribution (third distribution). Both the exit and closing of the air can be effected according to requirements, on either side and in fact at any desired point. The mat fits any standard bed and any couch or standard sized sofa, whilst by means of the same warming, airing and drying and various packings and wrappings air or steam baths can be effected. Figs. 3-10 show a number of examples of use.

Fig. 3 shows the mat used as an air, hot-air or steam bath. In this arrangement the hot air mat may be used for warming, airing and drying of beds.

Fig. 4 shows a partial hot air bath for back, breast and body.

Fig. 5 shows the same arrangement for the buttocks and the two legs (also recumbent position).

Fig. 6 shows a like arrangement for one leg.

Fig. 7 shows an arrangement for the knee, lower leg and feet of both legs (also recumbent position).

Fig. 8 shows the same arrangement for both arms. Also adaptable by rolling singly for one arm only.

The arrangements according to Figs. 8-8 may also be used with suitable packings, wrappings and the like as a heat distributing layer.

Fig. 9 shows an arrangement for treating the head, neck, the wind pipes—hot air inhalation—and the shoulder, and

Fig. 10 shows the use of the mat as hot air bed for children or prematurely born children (in this case air-douch with temperature regulator).

In addition the mat can serve directly for warming the seats of motor cars, electric railways and the like and indirectly for heating the latter.

What I claim is:

1. A hot air mat comprising a covering, a wire netting therein, flexible metallic tubing embedded in said wire netting, a common hot air inlet for the tubing, and means in the wall of the tubing permitting the passage of air.

2. A hot air mat comprising a porous fabric covering, a wire netting therein, flexible metallic tubing embedded in said wire netting, a common hot-air inlet for the tubing, and means in the wall of the tubing permitting the passage of air.

3. A hot air mat comprising a covering, a wire netting therein, flexible metallic tubing spread out and fixed in said netting, outlet holes in said tubing, and at least one means for supplying air to the tubing.

4. A hot air mat comprising a porous fabric covering, a wire netting therein, flexible metallic tubing spread out and fixed in said wire netting, outlet holes in said tubing, a common air chamber connected with the tubing, and means for feeding the air chamber with heated air.

In testimony whereof I have signed my name to this specification.

KARL POPP.

Sept. 21, 1937.

R. S. GAUGLER
REFRIGERATING APPARATUS
Filed April 30, 1934

2,093,834

6 Sheets-Sheet 1

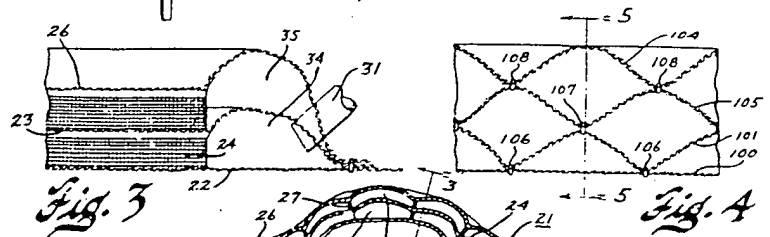
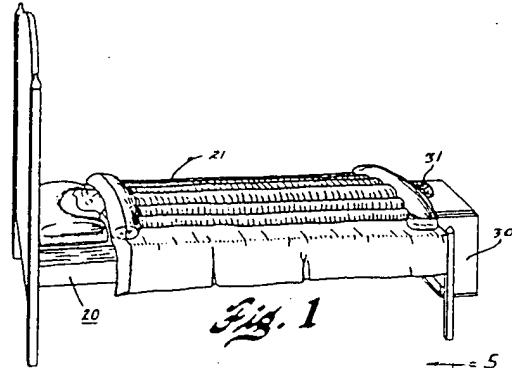


Fig. 3

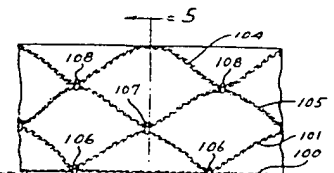


Fig. 4

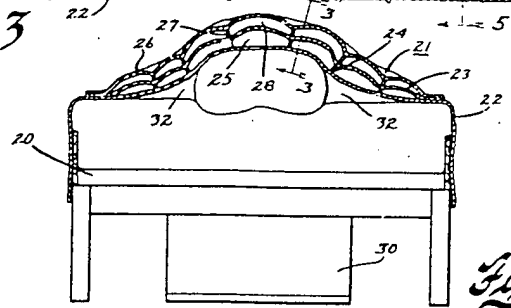


Fig. 2

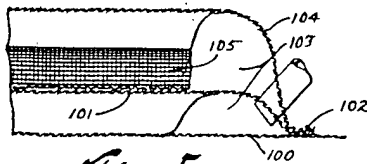


Fig. 5

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REFRIGERATING APPARATUS
Filed April 30, 1934

2,093,834

6 Sheets-Sheet 2

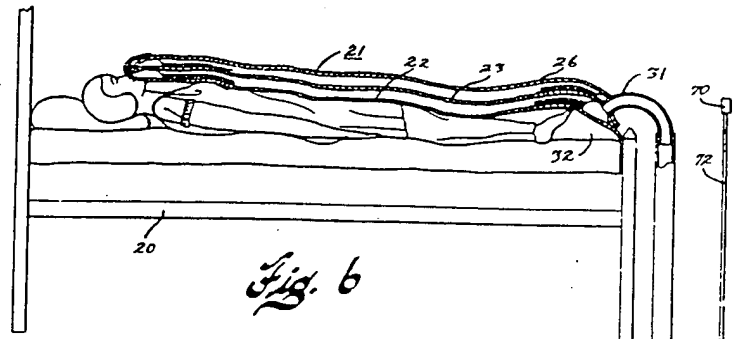


Fig. 6

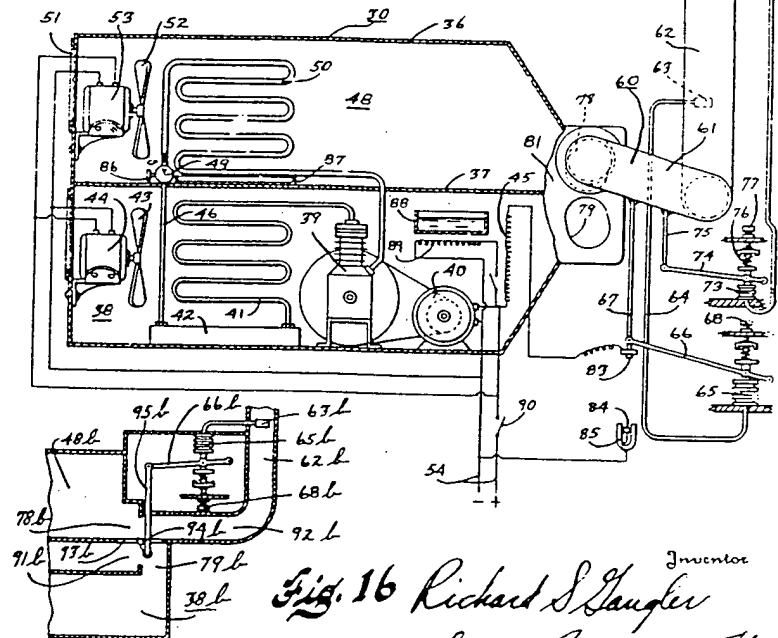


Fig. 16 Richard S. Gaugler

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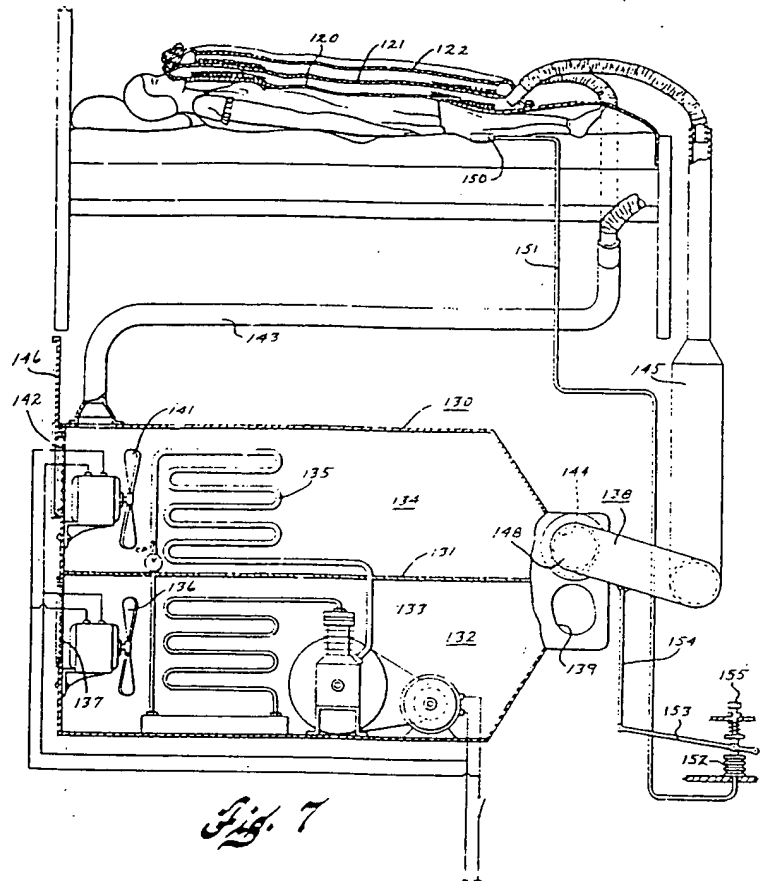
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2,093,834

REFRIGERATING APPARATUS

Filed April 30, 1934

6 Sheets-Sheet 3



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Filed April 30, 1934

2,093,834

6 Sheets-Sheet 4

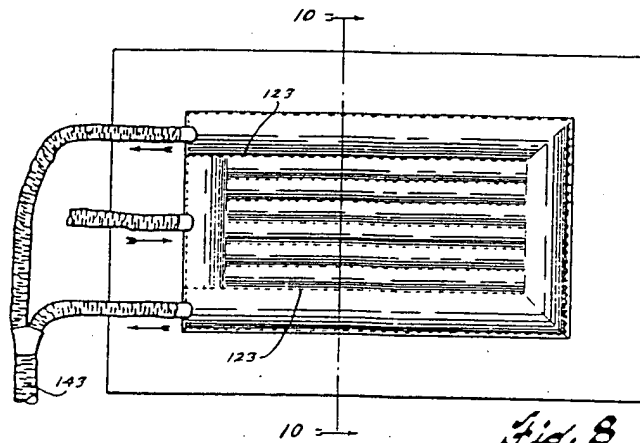


Fig. 8

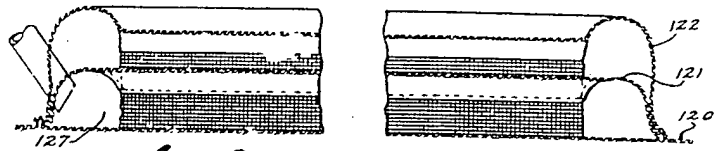


Fig. 9

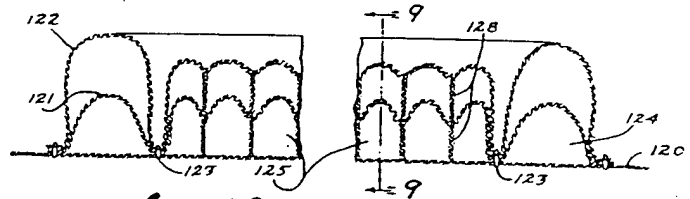


Fig. 10

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REFRIGERATING APPARATUS
Filed April 30, 1934

2,093,834

6 Sheets-Sheet 5

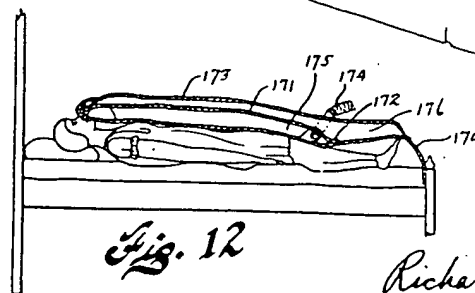
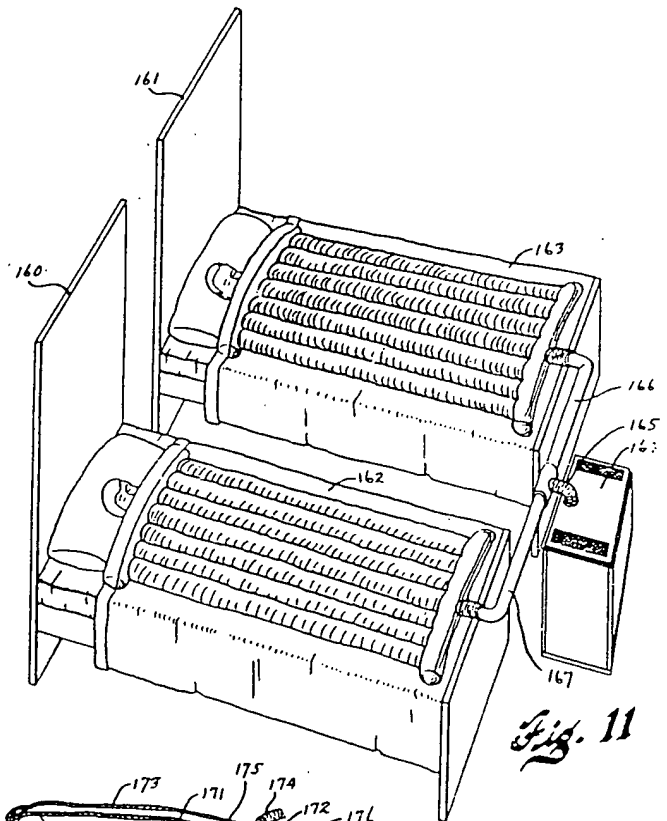


Fig. 12

Fig. 11

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Filed April 30, 1934

2,093,834

6 Sheets-Sheet 6

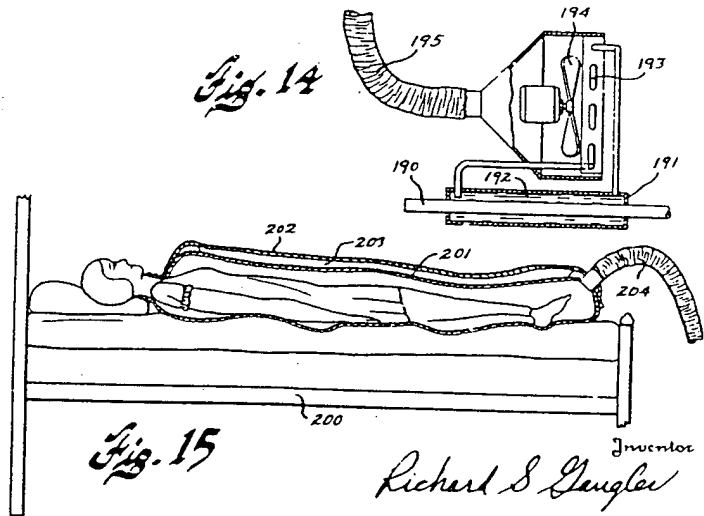
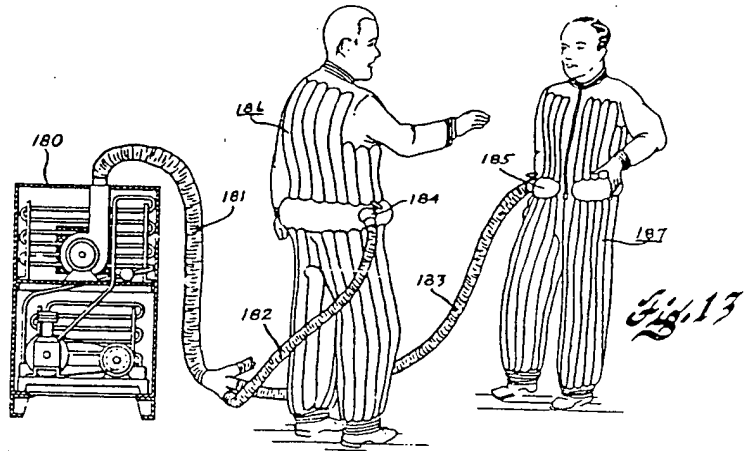


Fig. 15

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UNITED STATES PATENT OFFICE

2,093,834

REFRIGERATING APPARATUS

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Application April 30, 1934, Serial No. 723,078

11 Claims. (Cl. 128-145)

This invention relates to refrigerating apparatus and more particularly to a personal type of air conditioning.

Heretofore air conditioning equipment has been required to condition the air within the entire room or space occupied by persons desiring the comfort of air conditioning. If air conditioning were confined to the immediate vicinity of such persons, the equipment would be much less expensive both in initial cost and in operating expense. An application of this scheme which appears to have great possibilities is that of air conditioning beds since every one spends a continuous period of about one-third of each day in bed.

Attempts have been made to provide air conditioning enclosures for beds, some of which provide a complete enclosure for the bed while another merely provides curtains around the sides of the bed into which the cool air is introduced and confined therein by gravity. The general public, however, is unaccustomed to such enclosures and would experience a feeling of confinement which would prevent their widespread use. In addition, the initial cost of such enclosures is considerable and the operating expenses, while less than for a complete room, are still sufficiently high to prevent their use for those of limited means.

I, by my invention, propose to overcome these objections and to provide a personal type of air conditioning means which in outward appearance and in its use is little different from those replaced thereby and which also is sufficiently low in initial cost and operating expense to permit its purchase and use by persons of limited means.

My air conditioned enclosure employs a covering or enclosure for the body very similar as to material as well as to use and appearance to that now in ordinary use providing therein a means for diffusing the discharge of conditioned air over and surrounding the body to provide an air conditioned environment for the body as well as providing insulating air pockets, and to this enclosure I supply conditioned air or treating medium from a small inexpensive air conditioning or treating device capable of heating and cooling the air as required at a low operating cost.

More specifically I provide a covering for the body formed of ordinary fabric cloth or sheeting in a plurality of layers sewed or held together to form a plurality of enclosures into one of which I supply the conditioned air or treating medium from which some of the air diffuses through the sheeting into contact with the body to provide an

air conditioned environment for the body while some air diffuses through the sheeting into a second enclosure to form an inflated insulating air layer.

Further objects and advantages of the present invention will be apparent from the following description, reference being had to the accompanying drawings, wherein a preferred form of the present invention is clearly shown.

In the drawings:

Fig. 1 is a perspective view of one form of my invention;

Fig. 2 is a transverse sectional view through the mid portion of Fig. 1;

Fig. 3 is a fragmentary sectional view taken along the line 3-3 of Fig. 2;

Fig. 4 is a modified fragmentary section similar to that shown in Fig. 2;

Fig. 5 is a sectional view along the line 5-5 of Fig. 4;

Fig. 6 discloses a longitudinal sectional view of the bed shown in Fig. 1 together with a diagrammatic illustration of the air conditioning apparatus and system therefor;

Fig. 7 discloses a sectional view of a bed together with an air conditioning system, shown diagrammatically, illustrating a modified form of my invention embodying recirculation of the air;

Fig. 8 is a plan view of the air blanket shown in Fig. 7;

Fig. 9 is a longitudinal sectional view of the air blanket shown in Fig. 8 taken along the line 9-9 of Fig. 10;

Fig. 10 is a transverse sectional view of the air blanket taken along the line 10-10 of Fig. 8;

Fig. 11 is a perspective view disclosing a multiple air conditioning system embodying my invention applicable to twin beds;

Fig. 12 is a longitudinal sectional view through a bed embodying another form of my invention;

Fig. 13 discloses another application of my invention, particularly intended for persons required to work in hot or cold places;

Fig. 14 discloses a heating apparatus for the air conditioning suits shown in Fig. 13 suitable for use in an airplane, and

Fig. 15 discloses another application of my invention in the form of a sleeping bag.

Fig. 16 is a diagrammatic view of a simplified form of control apparatus.

Referring to the drawings and more particularly to Fig. 1, there is shown an ordinary wooden bed 20 provided with springs, a mattress and a pillow in the usual manner together with the

usual sheet covering the mattress. However, instead of the ordinary blankets or other bed clothing, I provide what I term an air blanket generally designated by reference character 21. This air blanket preferably is made up of a plurality of layers or sheet portions of muslin or percale sheeting or other suitable material as best shown in Fig. 2. The lower layer or sheet portion of this air blanket, designated by the reference character 22, is preferably a sheet similar in size to an ordinary bed sheet and may be formed out of similar material which is porous to a certain degree. This sheet extends over the sides and lower end of the bed.

Upon the upper side of the sheet I sew or otherwise suitably fasten a second sheet portion designated by the reference character 23 which may also be made of a similar porous material such as muslin or percale sheeting. This provides an air space between the sheet portion 23 and the sheet 22. In order to prevent the excessive bulging of the sheets when air is supplied to this air space, I connect this sheet and sheet portion by ordinary fabric mesh, screening, or netting designated by reference character 24. This permits the free flow of air through this enclosure and yet prevents excessive bulging of the sheet portion 23.

On top of the sheet portion 23 I provide a second sheet portion 26 which is fastened to the first sheet portion 23 and the sheet 22 by being sewed therethrough around its edge portions and also by being connected at intermediate points by fabric webbing, netting or screening designated by reference character 27 in a manner similar to the netting or screening designated as 24. This provides a second air enclosure 28 between the top sheet portion 26 and the intermediate sheet portion 23. This top sheet portion 26 may be made of the same material as the other sheet portions but if desired may be made of some impervious material.

At the foot of the bed or some other convenient place I place an air conditioning apparatus 30 enclosed in a neat attractive cabinet which may resemble an ordinary night table. This cabinet may either heat or cool the air and supply the air under pressure through flexible tubing 31 to cross duct 34 which distributes the flow of air within the air space or enclosure 25 formed between the lower sheet or sheet portion 22 and the intermediate sheet portion 23. From this enclosure 25 the air which is under a supplied pressure will diffuse through the sheet 22 into the spaces such as the space 32 beneath the air blanket to provide an air conditioned environment surrounding the body of the person sleeping in the bed. Preferably a sufficient supply of air is provided and preferably the air diffuses through the sheet 22 at a sufficient rate so that the air beneath the blanket is of substantially the same temperature as the air which is supplied by the air conditioning apparatus. This will provide an immediate environment of conditioned air surrounding the person sleeping in the bed. The air is also filtered in its diffusion through the sheet 22.

Most of the air which thus diffuses through the sheet 22 into the spaces beneath the air blanket escapes around the head of the person sleeping in the bed and thus provides conditioned air around the head of the person. If desired, the upper end of the air blanket may be pulled over the nose of the person so that the person will breathe the conditioned air. This is particularly

beneficial to persons afflicted with hay-fever and asthma. While most of the air which is supplied to the air space or enclosure 25 diffuses through the sheet 22 into contact with the persons sleeping in the bed, some diffuses through the intermediate sheet portion 23 into the second enclosure or air space 28, thus forming an insulating air space or insulating air pockets. If the top sheet portion 26 is made of a porous material, a slow diffused flow of air is thus provided into and out of the insulating air space 28 thereby carrying away and disposing of any heat leakage from the air in the room so that this insulating air space is maintained at substantially the temperature of the conditioned air supplied to the air blanket and in this way heat transfer is prevented between the air conditioned enclosure beneath the air blanket and the air in the room since the mattress of the bed provides excellent insulation beneath the person and the air conditioned enclosure surrounding the person sleeping. The air blanket may be provided with cross ducts 34 and 35 at the head and foot ends of the blanket as shown in Fig. 3 merely by stopping the mesh or screening 24 and 27 short of the head and the foot ends of the intermediate and top sheet portions 23 and 26. The fastening together of the sheet and sheet portion by the mesh or screen portions 24 and 27 provides the air blanket with a pleasing fluted appearance when it is inflated with conditioned air. During the daytime when the apparatus is not in use the air blanket may be covered by a spread as is customary. This air blanket is washable and may be readily washed in the usual manner similar to ordinary bed sheets.

Referring now more particularly to Fig. 6, for a disclosure of the air conditioning apparatus proper and its application to the air blanket there is illustrated diagrammatically the cabinet 30 having outer walls 36 forming an enclosure which is divided into two parts by a partition 37. Within one of the enclosures 38 formed thereby there is provided a refrigerant compressing apparatus including a refrigerant compressor 39 driven by an electric motor 40 for compressing the refrigerant and forwarding the compressed refrigerant to a condenser 41 where the compressed refrigerant is quenched and collected in a receiver 42. The condenser 41 and the compressor 39 are cooled by a blast of air provided by the fan 43 driven by the electric fan motor 44 and which creates a pressure within the enclosure 38. By discharging or blowing air over the warm condenser, compressor and electric motor, these units of the refrigerating system are cooled and a source of heated air is provided. This heating may be augmented by providing an electric heater 45.

The refrigerant liquefied by the refrigerant condensing apparatus located within the chamber or compartment 38 is conducted through a refrigerant supply conduit 46 into the compartment 48 where a suitable expansion valve or restrictor 49 is provided for controlling the flow of liquid refrigerant through the evaporator 50. Air from the room is drawn through a screened opening 51 into the enclosure 48 by a fan 52 which is driven by an electric fan motor 53 connected in parallel electric circuit relation with the fan motor 44 and the electric compressor motor 40 to a source of electric energy 54. The fan 52 discharges a blast of air over the cold surfaces of the evaporator 50 and creates a pres-

sure within the enclosure 48 to provide a source of cooled air.

Any suitable form of control means may be employed for maintaining the air supplied to the air blanket at a proper temperature but as a preferred form I provide an air selecting or mixing device 60 comprising a pivoted duct arm 61 communicating with the discharge duct 62 connecting through the flexible tubing 21 to the air space 25 in the air blanket and capable of selective communication with the enclosures 38 and 48 within the air conditioned cabinet to provide either heated or cooled air or any required mixture thereof in order to provide the proper supply of air at a proper temperature and humidity to the air space 25 within the air blanket 21. This pivoted duct portion 61 may be automatically moved to its proper selective position by a thermostatic control means which includes a thermostatic bulb 63 charged with a volatile or expansive fluid and located in the air stream of the outlet or discharge duct 62. This thermostatic bulb is connected by tubing 64 to a bellows 65 which operates a lever 66 connected by a link 67 to the pivoted selective duct portion 61.

This temperature control mechanism is provided with a selective manual adjustment 68 comprising spring means and a threaded adjusting means for varying the tension upon the spring means which opposes the expansion of the bellows in varying degrees according to the adjustment thereof so as to make it possible to secure almost any desired temperature of air in the outlet duct 62. However, for ordinary purposes I find that a temperature of between 75° F. and 85° F. is most suitable. Where the air temperature of the room is either greatly warmer or greatly colder than normal, an additional temperature control may be provided including a thermostatic bulb 70 charged with a volatile or thermal expansive fluid and located within the free air within the room. This thermostatic bulb 70 is connected by tubing 72 to a small metal bellows 73 connected by a multiplying lever 74 and a link 75 to the pivoted duct portion 61 so as to compensate for the effect of the air temperature of the room upon the heat transfer conditions between the air conditioned space beneath the blanket and the air in the room. This temperature control may also be provided with an adjustable regulating spring 76 and a threaded adjusting means 77 to regulate the amount of room temperature compensation provided in the selective thermostatic control.

The pivoted duct portion under the control of the temperature regulating apparatus is moved so that its mouth or inlet portion 61 selectively communicates with the outlet ports 78 and 79 of the air cooling enclosure 48 and the air heating enclosure 38. When the mouth 61 of the pivoted duct portion 61 is in direct communication with the port 78 the maximum cooling is obtained. In intermediate positions the mouth 61 of the pivoted duct means 61 may communicate partly with the port 78 and partly with the port 79 so as to supply a mixture of cooled and heated air to the space 25 of the air blanket. In order to supply warm air, the mouth 61 may move to a position in direct communication with the port 79 whereby heated air is supplied to the air space 25. If more heating is required, the electric heater 45 is supplied with electric energy by the closing of the switch contacts 83 and 84, of which the contact 83 is connected to the link 67 so that when the pivoted duct means

is moved to the extreme heating position, this contact 83 makes engagement with its cooperating contact 84 to close the electric heater circuit 45. In this way sufficiently heated air may be provided even when the room temperature is rather cold. A permanent magnet 85 is provided to prevent arcing of the contacts in opening and closing.

The humidity of the cooled air may be controlled by the temperature of the evaporating means 86. The temperature of the evaporating means 86 may be controlled by a manual adjusting means 88 provided upon the expansion valve 49 so as to control the evaporating temperature within the evaporator 80 and by this means it is possible to bring the temperature of the air to be cooled below its dew point so as to condense moisture therefrom. This moisture may be collected in a drip pan 87 located beneath the evaporator 80.

Likewise, means may be provided for humidifying the warm air when desired by providing a pan 88 containing water which rests upon an electric heater coil 89 connected in parallel electric circuit relation with the electric heater 45. This electric heater 89 evaporates the water at a desired rate in order to supply additional humidity to the air when hot air is required for the air blanket. By employing this humidifying apparatus and by suitably regulating the temperature regulating apparatus to obtain the maximum heating of the air, this apparatus may be employed to produce a mild fever in the person in the bed. In order to use the apparatus for producing a fever the adjusting screws 77 and 68 are adjusted so as to increase the tension upon the loading springs for the bellows 65 and 73 preferably as far as possible so as to raise the temperature of the air delivered to the bed to 130 or 140° F. The knife switch which controls the energization of the heater 89 is closed and the receptacle 88 is provided with an ample supply of hot water. Under such an adjustment the pivoted duct portion 61 will move to cover the opening 79 and the contacts 83 and 84 will be closed so that the heater 45 as well as the heater 89 will be in operation and by heating the water in the receptacle 88 and by heating the air by the compressing apparatus and the electric heater the temperature of the air and the humidity will be raised to a point which will cause a fever. The production of a fever may be aided by having a room temperature in which the apparatus is located as high as possible. The use of artificially created fever has been found very useful in treating certain diseases, and with this apparatus, may conveniently be used as an effective treatment for common colds. Medicinal compounds may also be placed within the pan 88 to form beneficial vapors. For convenience and clearness, the fans 43 and 52 have been shown as of the propeller type, but because of the higher efficiency I prefer to use the centrifugal type of fan in each case in order to efficiently provide the necessary air pressure for supplying the conditioned air under pressure to the air space 25 of the air blanket 21. The entire apparatus may be controlled by a manual switch 90.

If desired, other means for heating and cooling may be employed such as electric heaters, steam, hot water, or hot air from a heating system for providing heated air while ice, solidified carbon dioxide, cold water, or cold air may be employed for providing cold air for my air blanket.

In Figs. 4 and 5 a modified form of air blanket

is shown. In this form a full size sheet of muslin or percale sheeting is employed upon the bottom, this being designated by the reference character 100. Sewed to this full size sheet is a second or

intermediate smaller sized sheet portion 101 of a similar material which is sewed to the full size sheet 100 around the edges thereof and as shown at 102 and is also sewed longitudinally with the stitching in parallel but which stitching terminates short of the head and foot ends of the sheet portion so as to provide cross manifolds, such as the manifold 103, at the foot and head ends of the air blanket. A third or top sheet portion 104 is likewise sewed to the intermediate sheet portion 101 and the full size sheet 100 by being sewed to the other sheet portions around its edges as shown at 102 in order to provide the second air space or enclosure. The top sheet portion 104 and the intermediate sheet portion 101 are connected together to prevent bulging, and to present a fluted appearance, by cords or fish netting 105 extending in a zigzag fashion between the sheet portions and which is sewed or fastened to the intermediate sheet portion at the mid points between the sewed connections 106 by the knotting or stitching 107 and is fastened to the top sheet portion by knotting or stitching 108 which is located at the intermediate points of the cord or netting 105 between the stitchings 107. This form provides an air blanket of an attractive fluted appearance which may be easily made.

In Fig. 7, I have shown an air blanket type of air conditioning system which provides for the recirculation of the cooling air. In this air blanket there is shown a lower full sized sheet 120 to which are fastened, by sewing around the edges thereof, sheet portions 121 and 122 of substantially equal size. These sheets and sheet portions may be made of any suitable material such as a muslin or percale sheeting. These sheet portions are preferably sewed to the full size sheet 120 by sewing or stitching around their edge portions. It should be noted that in this form the upper sheet portions 121 and 122 are shorter than those found in the form shown in Fig. 6. This air blanket has been made in this way so as to prevent the cooling of the feet. It has been found that some persons feel uncomfortable if their feet are cooled as much as the remainder of their body and for this reason the air blanket shown in Fig. 7 is not provided with the air spaces extending over the feet.

The air blanket 120 shown in longitudinal section in Fig. 7 is better shown in Figs. 8, 9 and 10. In this form of air blanket, as stated before, the sheet portions 121 and 122 are sewed to the full size sheet 120 by sewing around the edge portions of the sheet portions 121 and 122. In addition these sheet portions 121 and 122 are sewed to the full size sheet portion 120 along the dotted line 123 shown in Fig. 8 and in Fig. 10 to form a U-shaped return duct 124 in the blanket. The supply duct portions designated by the reference character 125 are formed in the intermediate portions of the air blanket. The air blanket is provided with a distributing air duct 127 located at the lower or foot end of the sheet portions, which duct distributes the incoming air through the fluted supply duct portions 128 through which the air flows until it reaches the outer U-shaped return duct 124 which extends across the head portion of the air blanket as well as along both side portions. The sheet portions 121 and 122 are connected together and to the full size sheet

120 by mesh or webbing 129 to form the fluted air blanket structure similar to the first described modification.

Referring now again to Fig. 7, there is shown an air conditioning cabinet or enclosure 130 provided with a dividing wall 131 dividing the enclosure into an air heating compartment 132 containing the refrigerant liquefying apparatus 133 and an air cooling enclosure or compartment 134 containing the refrigerant evaporator 135 which is connected through the wall or partition 131 to the refrigerant liquefying apparatus 133. An electrically driven fan 136 is provided for drawing in air from the room through the screen opening 137 and discharging the air over the warm surfaces of the refrigerant liquefying apparatus to heat the air. This heated air may be discharged into the air in the room or into the selective pivoted duct control means 138 through the port 139. An electrically driven fan 141 connected in electrical parallel circuit relation with the motor driven fan 136 and the electrically driven refrigerant liquefying apparatus is provided within the air cooling compartment 134 for drawing air from the room through the screened aperture 142 as well as from the return air duct 143 which connects at a plurality of points with the return air duct 124 in the air blanket 120. This air is discharged over the surfaces of the evaporator 135 which cools and dehumidifies the air as required and discharges the air through the outlet port 144 into the pivoted selective duct portion 138 of the discharge duct 145 when required or out into the room when heated air and not cooled air is required for supplying the proper temperature of air to the air blanket.

The amount of re-circulation may be controlled by the sliding door 146 which is provided for partially or wholly closing the screened opening 142 which permits the entrance of air from the room into the cooling compartment 134. The pivoted selective air duct portion 138 has a mouth 148 which is adapted to register with either of the outlet ports 139 or 144, wholly or partially, as required, in order to supply air at the proper temperature to the air blanket. This pivoted duct portion 138 is controlled by a charged thermostat bulb 150 located within the air conditioned enclosure beneath the air blanket within the bed and connected by the tubing 151 to the metal bellows 152 which through a multiplying lever 153 and a link 154 selectively controls the position of the pivoted duct portion 138 and the connection of its mouth with the outlet ports 139 and 144. Manual adjusting means 155 comprising a spring and adjusting screw acting upon the spring means to control the expansion of the metal bellows 152 is provided for regulating the temperature of the air supplied through the air blanket in order to provide an air conditioned environment according to the desires of the person sleeping beneath the blanket. As in the other embodiments the sheets and sheet portions are preferably made porous so that a considerable amount of air diffuses into the space beneath the air blanket and so provides an air conditioned environment for the person sleeping therein while a lesser portion diffuses into the air spaces provided between the intermediate sheet portion 121 and the upper or top sheet portion 122. If desired, this form of blanket may be used with the air conditioning system shown in Fig. 6.

In Fig. 11 there is shown an application of my invention to twin beds. In this figure twin beds 160 and 161 are each provided with the air

blankets 162 and 163 which may be similar to those illustrated in Figs. 1 to 6 or similar to that shown in Fig. 12. These air blankets 162 and 163 are supplied with properly conditioned air from an air conditioning unit 164 of ample size which discharges the conditioned air under pressure into an outlet duct 165 which conducts the air through a common air manifold 166 and 167 to the air blankets 162 and 163.

In Fig. 12 there is shown a longitudinal section of a bed and air blanket therefor comprising a full size bottom sheet 170 to which is sewed or otherwise suitably fastened an intermediate sheet portion 171 which extends from the head portion of the full size sheet 170 to a point designated by the reference character 172 which is about above the knees of the person sleeping in the bed beneath the blanket. This sheet portion 171 is preferably fastened to the full size sheet 170 by being sewed thereto around its edge portions and being connected by knotting, quilting or similar means at intermediate points to prevent the excessive inflation of this intermediate sheet portion 171. The top sheet portion 173, on the contrary, extends from the head portion of the full size sheet 170 to the extreme foot portion thereof so as to provide an air insulating space over the entire body of the person sleeping under the blanket.

Thus in this form the air is supplied from a suitable conditioning means like that shown in Fig. 6 by the supply duct 174 to the air space 175 between the intermediate sheet portion 171 and the full size sheet 170. From this air space 175 the air under pressure diffuses through the sheet 170 into direct contact with the body of the person sleeping thereunder in order to provide an air conditioned environment for the body while some of the air diffuses into the air insulating enclosure 176 which forms an insulating air space over the top of the air enclosure 175 as well as the feet of the person sleeping under the air blanket. This form is very comfortable for both winter and summer use.

In Fig. 13 there are shown two workmen provided with clothing into which cool air may be supplied from an air conditioning means 180 through a common supply duct 181 and individual supply ducts 182 and 183 under the control of the regulating valves 184 and 185. This clothing in the form of jumpers or air suits 186 and 187 may be made of three sheets or thicknesses of material sewed together so as to provide two air spaces in a manner similar to that of the previously described air blankets. The air is introduced into the air space closest to the body and this air diffuses therefrom in both directions, some into contact with the body and some into second air space which forms the air insulating space.

However, if desired, these suits may be made similar to the sleeping bag shown in Fig. 15 and the air discharged into the interior of the enclosure provided by the air suits and the air permitted to escape therefrom through one or more layers of the material used. Instead of the air conditioning device shown in Fig. 13 these suits may be supplied with compressed air from a compressed air line which is ordinarily rather cool and low in relative humidity. I find these suits are suitable for working in hot places such as around furnaces in industrial plants as well as for persons subjected to a cold environment such as those working in icehouses or out in the open. For extremely hot situations, the suits should be

made of asbestos or similar fireproof cloth; otherwise, ordinary cloth or fabric goods may be used.

These suits may also be used by aviators for high altitude flights and an apparatus like that shown in Fig. 14 may be used for this purpose. In Fig. 14 there is shown an exhaust pipe 190 of the internal combustion engine used for propelling the airplane and surrounding this pipe in heat exchange relation therewith is provided a water or liquid chamber 191 containing water or other fluid 192 which may be evaporated by the heat supplied by the hot exhaust gases. The evaporated liquid rises into the heat exchange device 193 formed of fins in serpentine tubing through which air is drawn by the electrically driven fan 194 in order to warm the air and this warm air is discharged through the air duct 195 to the air suits. While the air suits 186 and 187 are shown in the form of jumpers they may take any convenient form such as the form of an overcoat or other types of clothing.

In Fig. 15 there is shown a bed 200 provided with a sleeping bag 201 capable of receiving a human being and provided with an additional sheet portion 202 providing an insulating air space 203 around the top portions of the sleeping bag. The sleeping bag 201 completely surrounds the person therein except for the head thereof and is supplied with conditioned air through the air duct 204 which discharges directly into the interior of the bag 201 at some suitable point in a manner similar to that described for the air clothing in connection with Fig. 13.

In Fig. 16 there is disclosed a simplified form of control apparatus applicable to either of the forms of air conditioning apparatus illustrated diagrammatically in Figs. 6 and 7. In this simplified form, the enclosure containing the evaporating means and the cooled air under pressure is designated by the reference character 40b and is provided with an outlet 78b forming part of a butterfly type of double two-way control valve. The enclosure 38b contains the refrigerant liquefying means and warm air under pressure and is provided with an outlet 78b directly opposite the outlet 78b. An outlet 81b leading to the room is provided for discharging waste air while the discharge duct 62b connecting with the air blanket connects to the outlet 82b which is directly opposite the outlet 81b. A butterfly valve 92b controls the flow of air from the enclosures 40b and 38b into the discharge duct 62b and the room outlet according to the temperature requirements.

For this purpose, the butterfly valve 92b is provided with an actuating lever arm connected by a link 88b to a multiplying lever 86b operated by a metal bellows 85b under the control of a manually adjustable spring and screw control mechanism. This bellows 85b is connected by tubing to a thermostatic bulb 83b located within the discharge duct 62b and charged with a volatile or thermal expansive fluid.

According to the temperature requirements as measured by the thermostatic bulb 83b, the butterfly valve 92b is moved to assume various positions. The butterfly valve may be moved to one extreme position to provide a free flow of air from the cooled air or evaporator enclosure 40b to the discharge duct 62b and from the warm air enclosure 38b directly to the outlet 91b leading directly to the room. When the butterfly valve is moved substantially 90° from this position a free flow of air is provided from the cooled air enclosure to the outlet 91b leading to the

room and from the warm air enclosure 38b to the discharge duct 82b. Under control of the thermostat bulb 83b the butterfly valve 93b may be moved to any position from one of these extremes to the other in order that air of the proper temperature may be supplied automatically.

Thus, I have provided a personal type of air conditioning equipment which may be used by persons desiring air conditioning equipment with little or no change of personal habits and which is capable of widespread application and is low in both initial cost and operating expense.

While the form of embodiment of the invention as herein disclosed, constitutes a preferred form, it is to be understood that other forms might be adopted, all coming within the scope of the claims which follow.

What is claimed is as follows:

1. A ventilating means including an inflatable covering for the human body, said covering comprising at least three sheet portions of a flexible material held together to form a plurality of enclosures and means for continuously conducting air under pressure into one of the enclosures between two of the sheet portions to keep the covering inflated and in contact with the body, one of the sheet portions being porous to permit the continuous diffused escape of air therefrom into contact with the body.

2. A ventilating means including an inflatable covering for the human body, said covering comprising at least three sheet portions of a flexible material held together to form a plurality of enclosures and means for continuously conducting air under pressure into one of the enclosures between two of the sheet portions, said two sheet portions being porous to permit the diffused escape of air therefrom into contact with the body and into another of the enclosures.

3. A conditioning means including air tempering means, an inflatable covering for a human body, said covering comprising a porous flexible sheet means, said air tempering means including means forcing the air through the flexible sheet means into direct contact with the body, said air tempering means including temperature responsive means for selecting and providing air of the proper temperature for said flexible sheet means.

4. A conditioning means including air tempering means, an inflatable covering for a human body, said covering comprising a porous fabric sheet means, said air tempering means including means for forcing the air through the fabric sheet means into direct contact with the body, said air tempering means including means for conducting tempered air to the flexible sheet means, and means responsive to the air supplied to the flexible sheet means for controlling the air tempering means.

5. A conditioning means for the human body including body clothing having a plurality of layers of fabric forming a plurality of superimposed air spaces therebetween, and means for supplying air under pressure into one of the air spaces between the layers of fabric, said fabric permitting the diffused discharge of air therefrom into contact with the body.

6. A conditioning means including an inflatable covering for the human body, said covering comprising a plurality of sheet portions of a flexible material held together to form an enclosure, another sheet portion of a flexible material being joined to one of the above mentioned sheet portions to form a larger enclosure covering a larger

area, and means for introducing air into the first mentioned enclosure.

7. An inflatable article for providing a zone of ventilated air in the vicinity of a body, said article including at least three sheet portions of flexible material positioned one on top of the other and held together to form two enclosures between the sheets located one above the other, said sheet portions having means providing communication between said enclosures, one of said sheet portions nearest the body being porous to permit the diffused escape of a fluid from one of the enclosures, and means for continuously conducting air under pressure to one of said enclosures, to inflate the enclosures and to provide a diffused discharge of air upon the body.

8. An inflatable article for providing a zone of ventilated air in the vicinity of a body, said article including at least three sheet portions of flexible material positioned one on top of the other and held together to form two enclosures between the sheets located one above the other, said sheet portions having means providing communication between said enclosures, one of said sheet portions nearest the body being porous to permit the diffused escape of a fluid from one of the enclosures, means for connecting dispersed portions of said sheet portions to limit the distance between the sheets, and means for continuously conducting air under pressure to one of said enclosures, to inflate the enclosures and to provide a diffused discharge of air upon the body.

9. An inflatable article for providing a zone of ventilated air in the vicinity of a body, said article including at least three sheet portions of flexible material positioned one on top of the other and held together to form two enclosures between the sheets located one above the other, said sheet portions having means providing communication between said enclosures, said sheet portions being quilted to limit the distance between the sheets and to provide a neat tufted appearance, and means for conducting air to one of said enclosures.

10. An inflatable article for providing a zone of ventilated air in the vicinity of a body, said article comprising a plurality of sheet portions positioned upon one another and held together to form an enclosure between the sheet portions, means for conditioning air and conducting the conditioned air under pressure to said enclosure between the sheet portions, one of said sheet portions nearest the body being porous to provide for the discharge of air from the enclosure into contact with the body, and means responsive to the temperature of the air within said conducting means for controlling said conditioning means.

11. An inflatable article for providing a zone of ventilated air in the vicinity of a body, said article comprising a plurality of sheet portions positioned upon one another and held together to form an enclosure between the sheet portions, one of said sheet portions nearest the body being porous fabric to provide for the discharge of air from the enclosure into contact with the body, means for heating and cooling air, mixing means for providing any desired proportion of the heated and cooled air, temperature responsive means for selecting the proper proportion of heated and cooled air, and means for conducting the air selected by the temperature responsive means to said enclosure between the sheet portions.

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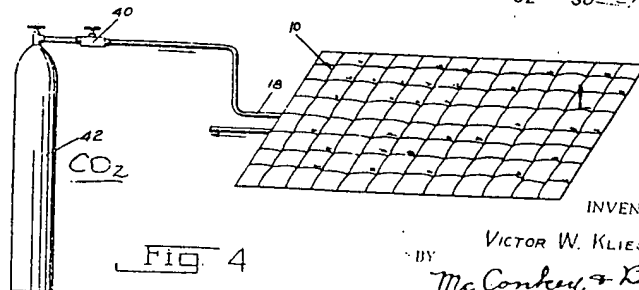
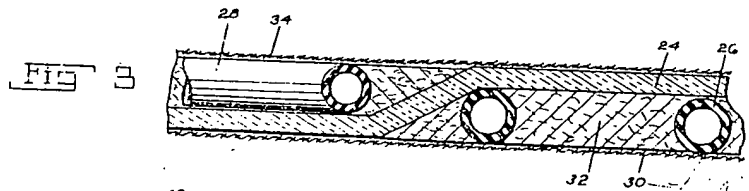
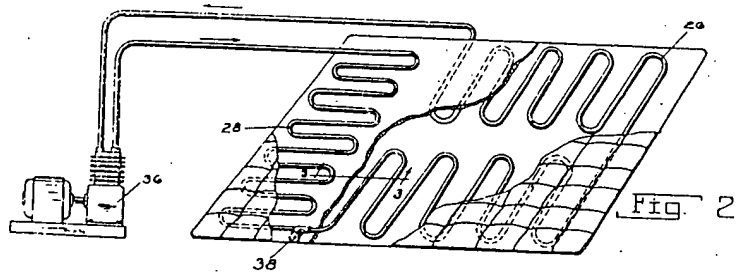
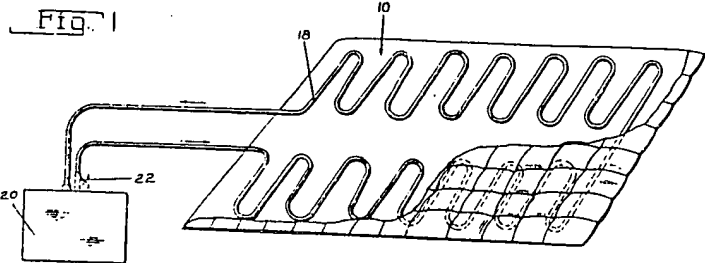
March 1, 1938.

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COVER

2,110,022

Filed July 15, 1935

2 Sheets-Sheet 1



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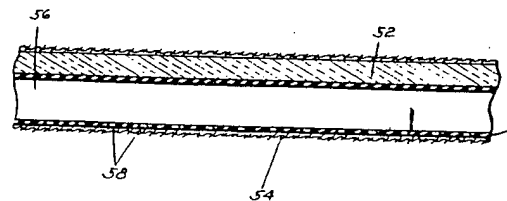
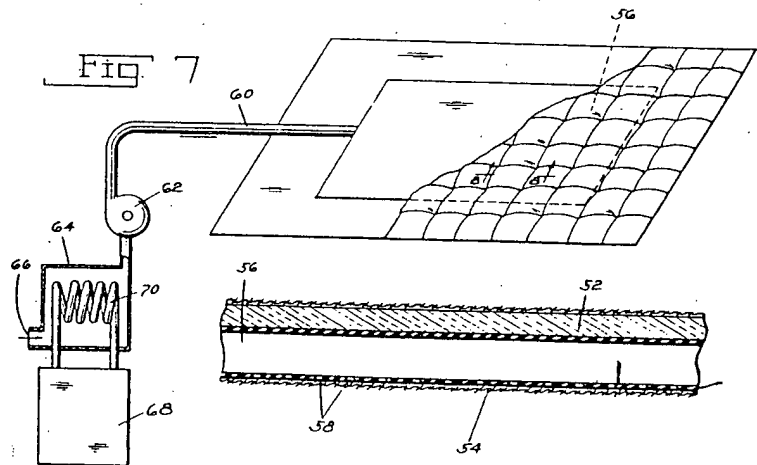
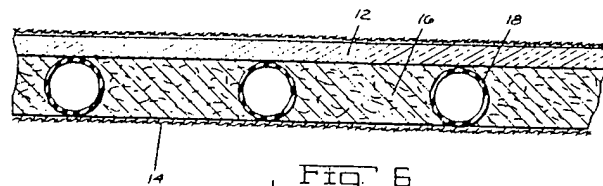
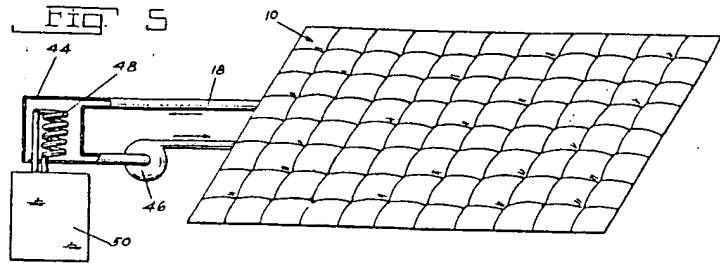
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2 Sheets-Sheet 2



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COVER

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Application July 15, 1935, Serial No. 31,540

3 Claims. (Cl. 5—334)

This invention relates to covers and more particularly to bed covers in which a heat transfer medium is circulated.

It is desirable to be able to control the temperature of a person in bed in order to provide comfortable conditions for sleeping during either extremely hot or extremely cold weather or in the treatment of diseases, for example in hospitals. If the temperature of the whole room is controlled a large volume of air must be conditioned requiring large expensive machinery and leading to high operating costs. It is accordingly one of the objects of the invention to provide a cover by which the temperature of a person in bed may be maintained at the desired value without requiring controlling the temperature of a large space.

Another object is to provide a cover which is cooled to cool a person using it.

Another object is to provide a cover which is connected to a source of cooling medium to circulate cooling medium through the cover.

According to one desirable arrangement, the above and other objects are produced by a cover including a layer of heat insulating material and a layer of heat conducting material arranged with means therebetween to circulate a heat transfer medium. The heat transfer medium may be a warm fluid or a cooling medium such as a refrigerant supplied by the usual compressor or may be air which is cooled by contact with a cooling coil. In case air is used, it may be circulated through a closed circuit or it may be discharged from the cover to pass over the body of the person using the cover.

Other objects, advantages and novel features will be apparent from the following description when taken in connection with the accompanying drawings, in which:

Figure 1 is a perspective view with parts broken away of a cover embodying the invention;

Figure 2 is a view similar to Figure 1 of a modified form of cover;

Figure 3 is a transverse section of the cover of Figure 2;

Figure 4 is a diagrammatic view illustrating a further modification;

Figure 5 is a diagrammatic view illustrating an arrangement in which air is circulated;

Figure 6 is a transverse section through the cover of Figures 1, 4, and 5;

Figure 7 is a view illustrating another modification, and

Figure 8 is a transverse section of the cover of Figure 7.

The cover of Figure 1 is shown as being a quilt

indicated generally at 10 and made up of an upper layer 12 (Figure 6) of heat insulating material such as a wool blanket and a lower layer 14 of heat conducting material such as a relatively thin sheet of cotton, linen, silk or the like. The two layers are spaced by a suitable filling material 15 such as loose cotton and a flexible conduit 16 of rubber or other suitable material is located in the filling material between the two layers.

The conduit 16 is connected to a refrigerating unit 20 of any desired type and which includes the usual condenser coil and compressing means. Refrigerant under pressure is discharged from the unit 20 through a regulating valve 22 and expands in the conduit 16 absorbing heat therefrom and is returned from the conduit 16 to be recompressed and condensed in the usual manner.

Thus the quilt 10 will be cooled and will cool a person using it without requiring cooling of the entire room. In use, the quilt is placed with the layer 14 of heat conducting material adjacent the body of the user to permit the ready transfer of heat from the user's body to the conduit 16 and with the insulating layer 12 on the outside to retard the transfer of heat from the outside to the refrigerant.

Figures 2 and 3 illustrate a modification of the arrangement of Figure 1 in which both the evaporating cooling coil and the condensing coil are embedded in the quilt. In this modification a heat insulating layer 24 extends along the top of the quilt over that portion in which the cooling coil 25 is embedded and along the bottom of the quilt under that portion in which the condensing coil 28 is embedded. The bottom of the quilt is covered with a suitable heat conducting layer 30 and the spaces between the convolutions of the cooling coil are filled with suitable filling material 32. The upper surface of the quilt over the condensing coil 28 is covered with a cloth cover 34 to permit the transfer of heat from the coil to the atmosphere of the room.

A suitable motor driven compressor 36 has its inlet connected to the cooling coil 25 and its outlet connected to the condensing coil 28, the two coils being connected by an expansion valve 38. Refrigerant from the cooling coil 25 is compressed in the compressor 36, condensed in the coil 28 and expanded through valve 38 into the coil 25 to absorb heat therefrom.

Figure 4 illustrates a modified arrangement in which a quilt 10 having a cooling coil 16 identical with that of Figures 1 and 6 is employed. In this arrangement one end of the coil 16 is

open to the atmosphere and the other end is connected through a regulating valve 40 with a tank 42 of compressed gas such as CO₂. Compressed gas from the tank 42 passes through the valve 40 and expands in the coil 18 in quilt 10 to absorb heat therefrom and is then discharged into the atmosphere.

Figure 5 illustrates a further modification employing a quilt 10 having a coil or conduit 18 identical with that of Figures 1, 4, and 6. In this modification the ends of the coil 18 are connected to a box 44 through which air is circulated by a blower 46. A cooling coil 48 is mounted in the box 44 and is connected to be supplied with refrigerant by a refrigerating unit 50 to cool air circulating through the box.

According to this construction cool air only is circulated through the quilt thus reducing the weight of the quilt and eliminating any possibility of refrigerant escaping from the cooling coil 18.

Figures 7 and 8 illustrate a quilt formed with an upper layer 52 of insulating material and a lower layer 54 of porous heat conducting material with a relatively flat bag 56 of rubber or other flexible material therebetween. The bag 56 is provided with a plurality of openings 58 in its lower surface and with an inlet conduit 60 through which air is forced by a blower 62.

The inlet of the blower 62 is connected to a box 64 having an inlet 66 opening into the atmosphere. A refrigerating unit 68 has an evaporator coil 70 mounted in the box 64 to cool air passing therethrough.

In use of the arrangement of Figures 7 and 8, air drawn into the inlet 66 is cooled by passing over the coil 70 and is forced through the conduit 60 into the bag 56 and out through the openings 58. Thus the cooled air from the bag 56 passes over the user providing both cooling and ventilation.

While several embodiments of the invention

have been shown and described, it will be apparent that many changes might be made therein and it is not my intention to be limited to any of the forms shown or otherwise than by the terms of the appended claims.

What is claimed is:

1. A bed cover comprising a layer of heat insulating material, an evaporator coil secured on one side of said material, a condenser coil secured on the other side of said material beside but not overlying said evaporator coil, an expansion valve connecting said coils, and a compressor having its inlet connected to said evaporator coil and its outlet connected to said condenser coil.

2. A cover comprising a layer of heat insulating material, an evaporator coil secured to one side of said layer, a layer of heat transfer material on the other side of said coil from the heat insulating layer, a condenser coil secured to the other side of said heat insulating layer from the evaporator coil, an expansion valve connecting said coils, a layer of heat transfer material on the side of said condenser coil opposite the heat insulating layer, and a compressor having its inlet connected to the evaporator coil and its outlet connected to said condenser coil.

3. A cover comprising a flexible layer of heat insulating material, a flexible rubber tube forming an evaporator coil and secured to one side of said layer, a layer of heat transfer material on the other side of said coil from the heat insulating layer, a flexible tube forming a condenser coil secured to the other side of said heat insulating layer from the evaporator coil, an expansion valve connecting said coils, a layer of heat transfer material on the other side of said condenser coil from the heat insulating layer, and a compressor having its inlet connected to the evaporator coil and its outlet connected to said condenser coil.

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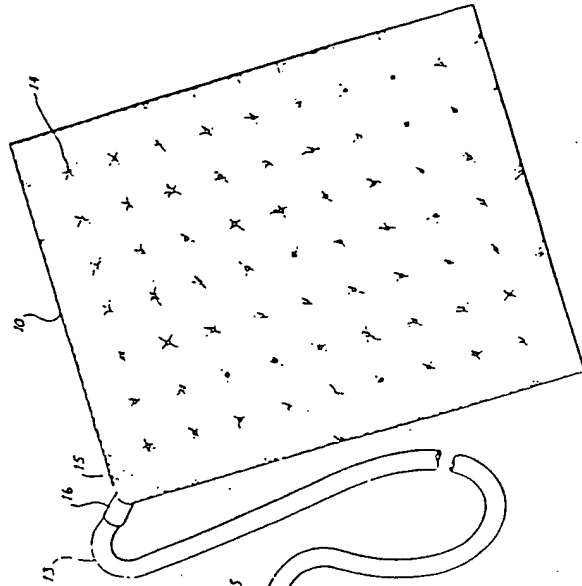
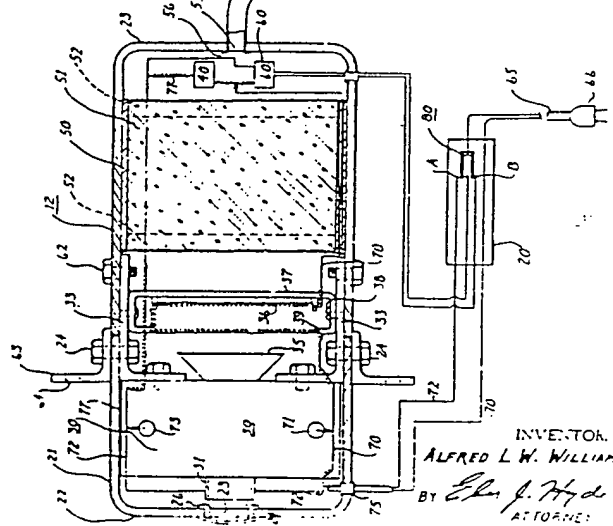


FIG. 1



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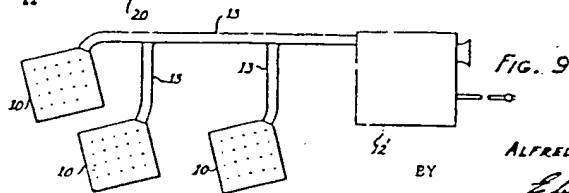
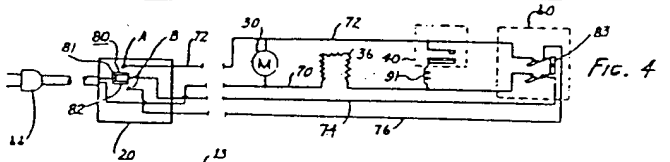
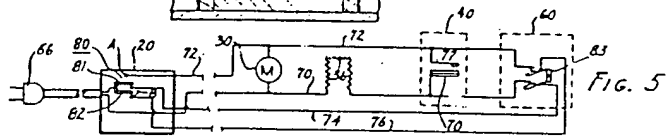
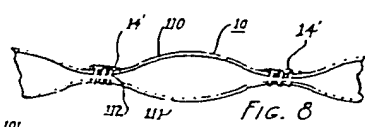
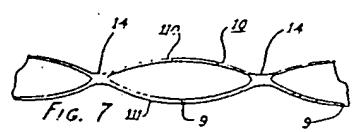
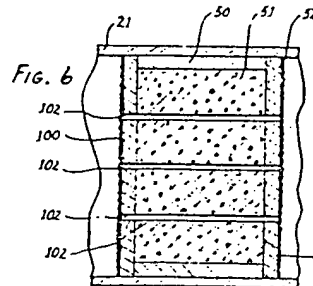
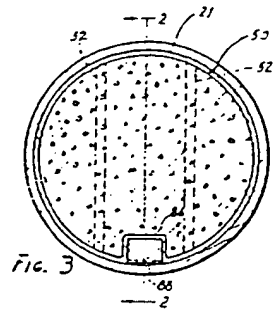
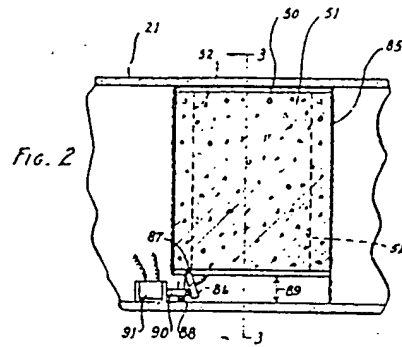
June 20, 1950

A. L. W. WILLIAMS
COMFORT UNIT

2,512,559

Filed Jan. 18, 1945

2 Sheets—Sheet 2



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UNITED STATES PATENT OFFICE

2,512,559

COMFORT UNIT

Alfred L. W. Williams, Cleveland Heights, Ohio

Application January 18, 1945, Serial No. 573,427

22 Claims. (Cl. 5-347)

1

My invention pertains to a comfort unit and more particularly to a pad or blanket or the like and an air conditioning unit associated therewith for heating a person or for giving the person a feeling of apparent coolness.

An object of my invention is to provide a comfort pad which may be used in bed or the like for heating a person.

Another object of my invention is to provide a comfort pad which may be used in bed or the like for giving a person a feeling of apparent coolness.

A further object of my invention is to provide a comfort pad which will warm a person or which will give the person a feeling of apparent coolness.

It is also an object of my invention to provide a small, compact, quiet, device for heating and/or apparently cooling a person.

Another object of my invention is to utilize the heating unit in a comfort device for maintaining the "cooling unit" in effective operation.

A further object of my invention is to provide a comfort pad for heating and/or apparently cooling a person which is automatically or semi-automatically controlled in accordance with thermostatic and humidity conditions.

Other objects and a fuller understanding of my invention may be had by referring to the following description and drawings, wherein,

Figure 1 illustrates partially schematically and partially in cross-section a comfort unit including a comfort pad and an air conditioning unit.

Figure 2 is a sectional view along lines 2-2 of Figure 1, showing a modified form of a portion of the air conditioning unit which may be used with the comfort pad shown in Figure 1.

Figure 3 is a sectional view along line 3-3 of Figure 2.

Figure 4 is a circuit diagram of the modified form of my invention shown in Figures 2 and 3.

Figure 5 is a circuit diagram of the form of my invention shown in Figure 1.

Figure 6 illustrates a further modified form of my invention.

Figures 7 and 8 are enlarged cross-sectional views of portions of two types of comfort pads which may be used in my invention, and

Figure 9 schematically illustrates a multiple installation utilizing my invention.

With respect to Figure 1, the invention comprises a pad or blanket unit 10 which is connected to an air conditioning unit, indicated generally by the reference character 12, by means of a hollow air impervious tube 13 of suitable length.

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The comfort pad or blanket unit 10 may comprise any material through which a small amount of previously conditioned air may be caused to flow. And it may be positioned near a person so that the conditioned air which flows out of it will come into contact with the body of a person; or the comfort pad 10 may be a mattress or pillow upon which a person may lie.

I prefer to utilize a pad comprised of two sheets of substantially air impervious material; these two sheets being connected together at their edges and at a plurality of spots 14 throughout their area as is shown in Figure 7. One sheet of this pad has a plurality of small holes, such as pin holes 9 in it, through which the conditioned air furnished to the pad passes.

The material from which the pad 10 is made is relatively immaterial so far as my system is concerned. However, I prefer to utilize "Koroseal" sheets, as the material is very pliable, is air impervious except where small pin holes are made, and does not rustle when it is bent and crumpled. This lack of rustle is of advantage when my pad is used by a sleeping person as occasional turning and tossing about will not cause noise to wake the person up. Further, when a material such as "Koroseal" is utilized the connections 14 and the edge seal between the upper and lower layers may be made by momentarily applying an amount of heat sufficient to slightly melt the "Koroseal" while simultaneously or immediately thereafter applying pressure while the spot cools to cause the two layers to "weld" together. This may be called "spot welding" as the two sheets become integral at the edges at the spot 14. It is also within the scope of my invention to sew the two layers together either in spots or in long lines, and to seal the needle holes in one of the layers by means of any hardenable sealing material but leaving the needle holes in the other layer for the air to escape as shown by Figure 8.

The hose 13 may be connected to one corner of the pad 10 by any suitable means such as the flat funnel 15 which may be comprised of plastic, metal, or the like, and which extends inside the corner of the pad. One end of the hose 13 may slip in the tube-like portion 16 which is integral with funnel 15 and may be suitably connected thereto by clamping or gluing or by friction. Air which is blown through the hose 13 thereby enters the interior of the pad 10 and due to the slight amount of pressure which is built up by the resistance of the air to passing out through the small pin holes in the pad a slight bal-

action or puffing of the pad is obtained. The plurality of points 14 where the two sheets comprising the pad are connected together prevent the pad from becoming too thick when it puffs up. The slight pressure, say, for instance, 1 to 2 ounces, is sufficient to cause a flow of air through the numerous pin holes 9 in one side of the pad. Thus if the pad is thrown over a person with the pin-hole side down the air which flows out of the pad comes in contact with the person's body.

The pad 10 may be the size of a blanket so that it can be tucked in around the mattress, or it may comprise the center section of a composite blanket the edges of which are of ordinary blanket material and adapted to tuck in around the mattress. The center section of the composite blanket would comprise the pad portion 10 which thereby is adapted to be positioned over that portion of a bed normally occupied by a person. Also, the pad may be small and adapted for insertion under the covers of a regular bed so that it would not need to be tucked in. It is also within the scope of my invention that the tube 13 may be connected to a mattress and the mattress may be air pervious or may have a plurality of holes by means of which the air could come in contact with the body of a person lying in bed.

Connected to the end of the hose 13 opposite the blanket end is an air conditioning unit indicated generally by the reference character 12, and a switching mechanism indicated generally by the reference character 20 is provided for controlling the air conditioning unit. Details of this switching mechanism 20 will be more fully described later.

The air conditioning unit 12 comprises a hollow tubular member or housing 21 which may be cylindrical or oval or any other shape in cross-section, and the member may be formed of metal, plastic, or spirally wound paper the successive windings of which are connected to each other by glue or plastic material to form a hard, rigid tubular member. This housing 21 has two end portions 22 and 23, integral respectively with two side wall portions. This construction facilitates assembly but it is to be understood that the housing 21 may comprise a single piece tubular member and the end portions 22, 23 may be connected thereto in any suitable manner. Through the end 22 there is an air inlet opening 23 having grill work 24 such as a plurality of finely spaced bars and/or a layer of cloth or the like for preventing the ingress of foreign matter into the housing 21. The grill 24 may be snapped into the housing and maintained there by means of spring lugs 25 or by any other suitable means.

Within the housing 21 and just inside the opening 23 there is positioned an air pump 30 having an opening 31 positioned closely adjacent the air inlet 23 into the housing 21. The air pump 30 is mounted on the wall of the housing 21 by means of angle irons 33 and nut and bolt devices 24, and comprises an electrically driven motor for driving an air impeller which may be any suitable type which delivers on the order of 5 to 10 cubic feet of air a minute at a pressure of about 1 or 2 ounces. The electric motor and pump should be sufficiently quiet in their operation that a person trying to sleep would not be disturbed either by noise or by vibrations. The air pump unit 30 has an outlet 35 from which the air is blown against a heater such as an electrically energized coil of resistance wire 36. The

resistance wire is mounted on the same angle irons 33 by means of a bar 37 of insulating material; the bar 37 being secured to the angle irons 33 by screws 38 or the like. A convenient method for connecting the resistance wire 36 to insulating member 37 is to thread it through holes 39 through the inwardly turned leg portions thereof.

Within the housing 21 there is a container 50 which may be comprised of light cardboard, heavy paper, metal, plastic or the like. The container is shaped to fit within the housing 21 with its wall portions snugly against the interior surface of the housing, and it has air pervious end closure means such as cloth stretched across the ends and connected to the walls of the container 50. Within the container 50 is a large amount of silica gel 51 or other moisture absorbing means. The cloth end closures prevent this silica gel 51 from spilling out of the container 50 into the housing 21 yet permit the air which flows through the container to pass through the container 50.

The end 23 of the housing 21 has an outlet opening 55 to which is connected one end of the hose 13. Any means may be utilized for connecting the hose at this outlet opening such as a number of spring clips 56. Mounted on the wall of the housing 21 preferably between the silica gel container 50 and the outlet opening 55 is a hygrometer 60 and a thermostat 40. These are schematically shown as a wide variety of commercially available hygrometers and thermostats may be utilized to control my air conditioning unit.

The angle irons 33 may be utilized for securing the two portions of the housing together. The bolt arrangement 24 secures one end of the housing 21 and a bolt arrangement 62 secures the other end of the housing to the angle iron 33. One or more externally mounted angle irons 63 may be connected to the housing 21 and to the internally mounted angle iron 33 by means of bolts 24, and each angle iron 63 may have a mounting hole 64 through which the conditioning unit may be connected to the frame of a bed. Other suitable arrangements for connecting the air conditioning unit 12 to a bed may be utilized, such as by swinging it in a hammock which is suspended from the bed. This will prevent vibration from being transmitted from the air conditioning unit to the frame of the bed. Also, any of the well known rubber mounting devices may be utilized to reduce the transmission of vibration to a bed.

The control panel 20 may be mounted on the head or on the side of the bed or, if desired, it may be a separate movable switch which may be positioned on a night table beside the bed. Connected to the control panel 20 is an electric cord 65 which may be plugged into any convenient source of electric power, such, for example, as a 110 v. 60 cycle, A. C. supply, by means of a plug 66. One side 70 of the electrical supply line may go to terminal 71 of the air pump unit 30 and the other side 72 of the supply line may be connected to terminal 73 of the air pump unit 30. The wires 70 and 72 extend through the housing 21 by means of a small hole drilled therein and this hole may be sealed by a grommet 75. The electric motor in the air pump unit 30 is in parallel with the electric heater coil 36, and the electrical circuit through the heater coil 36 extends to one of the electrical contacts 76 (see Figure 5) of the thermostat 40. The other

side of the motor circuit is connected to the thermostat 40 by means of wire 71. The thermostat 40 is arranged so that it opens the circuit through the heater 36 when it is satisfied.

The hygrostat 60 is in parallel with the thermostat 40 and independently of the thermostat 40 supplies actuating current to the electric motor in the air pump unit 30 for starting the pump, and at the same time completes a circuit through the heater coil 36. These functions are performed when the humidity within the housing 12 is high.

In the winter the air conditioning system operates as follows:

The thermostat 40, which may be manually adjustable over a wider range of temperatures, may be set to any temperature for keeping a person comfortable. The comfort pad 10 is thrown over a person either by itself or with blankets on top of it. The operator throws the switch 80 on the control panel 20 into position A. Power is thus supplied to the electrical driving unit in the air pump 30 which sucks in air through the opening 23 and blows it by means of tube 13 into the comfort pad 10 and from there it flows around a person's body. The thermostat 40, not being satisfied by the cool air which is being taken in at the inlet 23, establishes an electrical circuit through the heater 36 and the air which is blown out of pump outlet 35 is heated. This air passes through the silica gel 51 thereby heating the silica gel, and the warm air passes through tube 13 which may be heat insulated, into the comfort pad 10 from where it passes out of the small pin holes 9 and into contact with the body of the person in bed. Upon the thermostat 40 becoming satisfied by the heat supplied by the coil 36 it opens a circuit which breaks the current supply to the coil 36 thereby shutting off the heat. The air which is blown through the silica gel 51 after the heater has been turned off, is slightly warmed due to the heat that is stored in the silica gel but soon the thermostat will no longer be satisfied and will close the coil energizing circuit thereby supplying current to the heater 36.

While I have shown a heater device which is operated by a make-and-break thermostat it is also to be understood that it is within the scope of my invention to utilize a heater device which does not continually turn on and off but which supplies a relatively constant amount of heat and the thermostat operates to adjust the amount from zero to a large amount. The hygrostat 60 is not essential for the winter operation as large amounts of heat may be imparted to the air which is blown around the person, thus making the person feel warm regardless of the moisture content of the air.

It is well known that the comfort of a person depends upon several factors, among them being the temperature of the air, the humidity of the air, and the motion or velocity of the air surrounding the person. Thus, an amount of warm dry air having sufficient velocity will give a person the feeling of apparent coolness if it evaporates moisture from the skin of the person. It is this evaporation which makes the person apparently feel cool. In the winter warm dry air, if it evaporates moisture from the skin of a person, might make that person feel cool; whereas warm moist air would make him feel warm. In the device shown in Figure 1 dry air is supplied to the person. However, sufficient heat may be imparted to that air that the dryness thereof

becomes immaterial. The device shown in Figures 2 and 3, which is to be described in detail later, provides for supplying to a person warm air which has not been dehydrated and thus not as much heat need be imparted to the air.

In the summer when the air is warm and its moisture content is high, the device would operate as follows: The silica gel is dry. When the switch blade 80 is in position A the blower 30 is operating. Heater coil 36 is not energized as the temperature of the warm moist incoming air satisfies the thermostat 40 and its contacts are open to break the circuit through the coil. Hygrostat 60 is satisfied because the silica gel 51, being unsaturated, maintains the air within the container at a low moisture content. Thus its electrical circuit is broken. The warm moist air is forced through the silica gel container 50 where substantially all of its moisture is removed, and this dry air is blown onto the person in bed thereby making him feel cool due to the evaporation of the body moisture. Sufficient silica gel 51 is in the housing 21 for a number of hours of operation, such, for example, as 10 hours. This means that there must be sufficient silica gel to absorb the moisture from the air which passes through the container in ten hours of operation. Thus the volume of air which is blown about a person should be kept to a minimum. For this reason I provide pin holes only on the bottom layer of the material which comprises the pad 10.

After the device has been in operation all night the moisture which has been absorbed by the silica gel must be driven off in order to prepare the silica gel for the next night's operation. Thus, upon rising in the morning switch blade 80 is thrown into position B, where blade 81 establishes a circuit through wire 74, through switch 83 (when hygrostat switch is closed), and through the heater 36. Blade 82 establishes a circuit through wire 76, through switch 83 (when hygrostat switch is closed), and through wire 72 to energize the blower 30. The hygrostat switch will be closed due to the saturation or near saturation of the silica gel and thus the heater and blower will both be on regardless of the position of the thermostat switch 40, and hot air will be blown through the silica gel 51 thereby taking substantially all of the moisture out of the silica gel. When the silica gel 51 has become sufficiently dry or re-activated the air which is blown about the hygrostat 60 will become dry and the hygrostat will open the circuit B through the motor and through the heater thereby automatically shutting both of them off.

If the moisture content of the air which has been passing through the air conditioner during a night operation is not high enough to saturate the silica gel, then throwing switch blade 80 into position B will not cause the motor 30 and the heater 36 to be energized. The next night when the person wishes to retire, he throws switch 80 from position B into position A. This starts the electric motor which operates the electric blower to cause air to be blown through the silica gel 51 into the comfort pad 10. Due to the fact that the silica gel has either been re-activated or has not needed re-activation, the air which passes around the hygrostat will be relatively dry and will not cause the hygrostat 60 to try to establish a contact. However, should the silica gel become saturated due to long continued use without the operator throwing the switch 80 into position B no

harm will be done by the closing of the hygrostat contacts as circuit B is open at the switch 80.

Figures 2, 3, and 4 illustrate another form of my device. The silica gel unit 85 extends only part way across the housing 21. The remainder of the distance is closed by a flap arrangement 86 which is pivoted at 87 and which may seal against the abutment 88 for substantially preventing air from flowing through the passage-way 89. The flap 86 is under the control of a solenoid operated plunger 90 and the coil 91 of the solenoid operated plunger is arranged in the electrical circuit of the thermostat 40 as shown in the circuit diagram of Figure 4 so that when the thermostat 40 is not satisfied and is calling for heat the flap 86 is open allowing air to pass through the passage-way 89. Accordingly, in the winter time when heated air is being supplied to the comfort pad 10 substantially all of the air by-passes the silica gel and retains its moisture. Thus warm moist air is supplied to the person in bed rather than warm dry air, and it has been found that the amount of heat supplied to the air by the heater coil 36 in order that the person should feel a given degree of comfort is considerably less.

Silica gel and many of the other dehydrating agents have the characteristic of absorbing substantially all of the moisture in the air which passes through it until the silica gel reaches saturation, at which point the agent no longer absorbs any moisture. In other words, the silica gel, while active, takes substantially all of the moisture out of air. It is not always desirable or necessary to pass absolutely dry air around the body of the person in order to give him a feeling of comfort, and during very moist days the quantity of water to be absorbed during 10 hours of operation would be large, therefore requiring a large amount of silica gel in the housing with consequent higher pressure to force the air through the silica gel container. If, for instance, the atmosphere has 80% humidity and air of 40% humidity is blown about a person he will feel more comfortable. Accordingly, only a portion of the moisture in the air need be removed, thereby saving in silica gel and saving on the size of the unit.

Figure 6 illustrates a modified form of silica gel container for passing air to the comfort pad which is not substantially 100% dry. It comprises the container 50 having end closure means 51 similar to the end closure means in Figure 1. At the ends it has rigid supports 100 and 101 over which the cloth to retain the silica gel is stretched and to which it may be connected. Between these two supports extend a number of small air pipes 102. The silica gel 51 is positioned around these pipes and the air which passes through the pipes does not become dehydrated as it does not contact the silica gel. The pipes 102 preferably should be of such size and number that there is established a resistance to the flow of air therethrough which approximates the resistance to the flow through the silica gel. If the pipes were too large too much of the air would pass through them and not enough through the silica gel, resulting in insufficient dehydration of the air. If the resistance to the flow of air through the pipes 102 approximately equals the resistance to the flow of air through the silica gel then about one half of the air will pass through the silica gel and half will pass through the pipes. On a day which has, for example, 80% humidity, the humidity of the conditioned air of the comfort pad

will be about 40%. This is a sufficient drop to be readily noticeable by a person and would give an apparent feeling of coolness.

It is within the scope of my invention that moisture can be added to the air which is delivered through the comfort pad 12. This would be particularly valuable during dry winter nights. One method of adding moisture to the air would be to provide an opening in the top of the silica gel container 50 through which a small amount of water could be poured. The silica gel 51 will absorb this water and as warm air is forced through it, it will give the moisture up. Other methods which could be used would be to provide a tank of water with a wick of air pervious cloth or the like partially immersed in the water. Obviously a number of other methods could be used.

The comfort pad 10 has been described as comprising two sheets of material connected together at their edges and at a plurality of spots throughout its area to establish a hollow pad which does not "balloon" up when air under pressure is supplied to the pad.

Figures 7 and 8 illustrate two methods of connecting the two sheets 110 and 111 together. In Figure 7 the sheets have been "spot welded" together by applying to localized spots sufficient heat to soften the material and while the material cools pressure is applied. At the spot 114 the two sheets 110, 111 fuse together and become integral. Between the sheets at areas where they are not connected together the air is free to flow.

In Figure 8 the two sheets 110, 111 have been stitched together with thread 112, and the needle holes in the sheet 110 have been sealed by means of a hardenable material such as plastic cement, glue, shellac or the like to prevent air from escaping. The needle holes in the sheet 111 remain open for air to escape, thereby obviating the necessity for special air holes 9.

Figure 9 illustrates a multiple installation utilizing a plurality of comfort pads 10 connected to a single air conditioning unit 12' which obviously may be of a larger size than that used for a single pad. It is contemplated that hotels could have a central condition unit and pipes leading to all of the rooms. To these pipes the comfort pad shown in Figure 1 could be connected. In an installation of this size it would be economical to actually cool the air which is delivered.

While I have described my invention with a certain degree of particularity it is to be understood that numerous other arrangements of parts and many other different materials and processes of manufacture may be used without departing from my invention.

I claim as my invention:

1. In a comfort unit; the combination including enclosure means having a plurality of small holes therethrough and adapted to be positioned near a person; hose means one end of which is connected to said enclosure means; air conditioning means connected to the other end of said hose means, said air conditioning means including means for dehumidifying air; and means for forcing air through said dehumidifying means for dehumidifying said air and through said hose into said enclosure means from where it passes through the holes therein into contact with the body of the said person for establishing a cooling effect.

2. In a comfort unit; the combination including enclosure means having a plurality of small holes therethrough and adapted to be positioned

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15. In a comfort pad as described, a plurality of thin sheets of thermoplastic material disposed in face-to-face relationship and integrally connected together at a plurality of discrete locations throughout its area and connected integrally together in a continuous line about the peripheral edge thereof, said pad having an air inlet opening communicating with the space between said sheets and having a plurality of smaller air outlet openings, the said plurality of air outlet openings being in only one of said sheets.

16. An air conditioning device as set forth in claim 15, further characterized in that said means for conditioning the air comprises a chemical dehydrator adapted to attract and hold moisture.

17. In a comfort unit; the combination including a flexible pad defining an enclosure having a plurality of small holes therethrough and adapted to be positioned near a person; air conditioning means connected to said flexible pad and including a supply of a chemical dehydrator adapted to attract and hold moisture, and means for forcing air into contact with said chemical dehydrator for at least partially dehumidifying said air and thence into said pad from where it passes through said holes into contact with the body of the said person for establishing a cooling effect.

18. In a comfort unit; the combination including enclosure means having a plurality of small holes therethrough and adapted to be positioned near a person, a housing having an air inlet opening and an air outlet opening connected to said enclosure means, blower means for forcing air through said housing, moisture absorbing means within said housing for absorbing moisture from said air which is blown through said housing, means for heating the air which is blown through said housing, thermostat means for regulating the heating of said air, a hygrostat within said housing, electrical circuit means connected through said hygrostat to said blower and to said heater means, and switch means having a first and a second position, said switch means in said first switch position controlling said electrical circuit means to cause said blower and said heater means to operate together to blow warm air through said moisture absorbing means and out through said housing outlet independent of

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the position of said hygrostat, and in said second switch position controlling said electrical circuit means to cause said blower and said heater means to operate together only when the humidity within said housing satisfies said hygrostat to close the electrical circuit therethrough, said thermostat being operable when said switch means is in said first position to reduce the heat supplied by said heater means.

19. A comfort unit as set forth in claim 18, further characterized in this: that said thermostat means is adjustable to regulate the heat supplied by said heater means.

20. A comfort unit as set forth in claim 18, further characterized in this: that said moisture absorbing means comprises silica gel through which the air blown through said housing must pass.

21. A comfort unit as set forth in claim 18, further characterized in this: that all of the air which passes through said housing passes through said moisture absorbing means.

22. A comfort unit as set forth in claim 18, further characterized in this: that only part of the air which passes through said housing passes through said moisture absorbing means.

ALFRED L. W. WILLIAMS.

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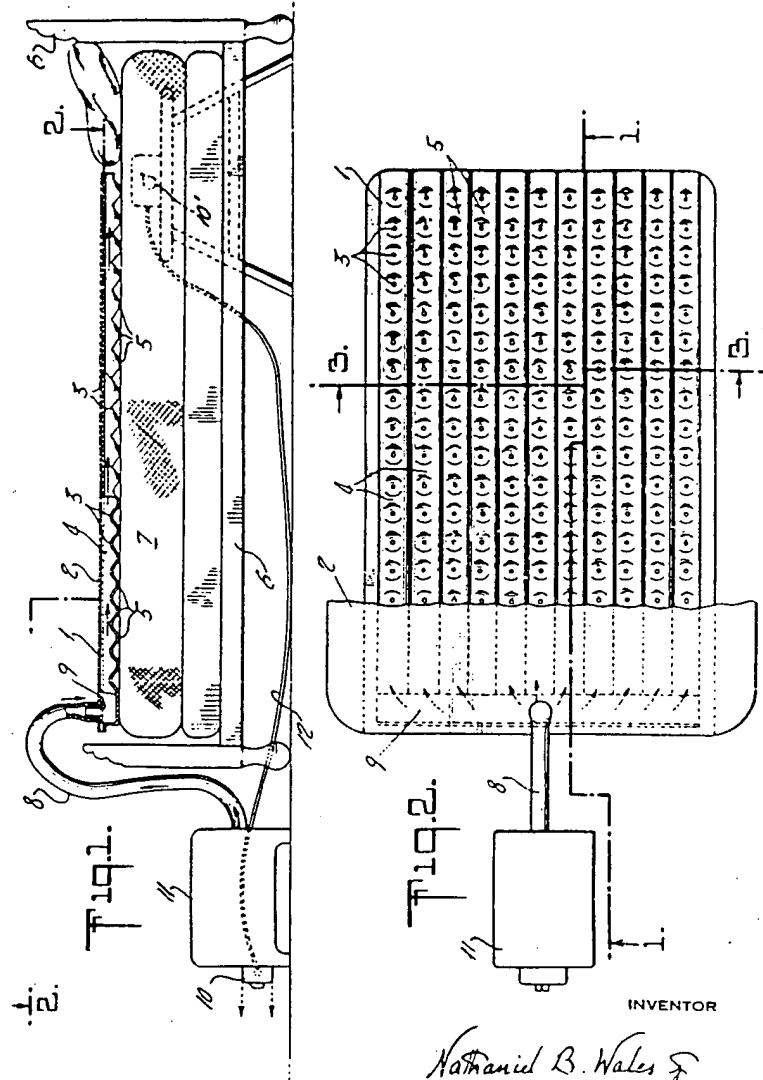
N. B. WALES, JR

2,601,189

AIR COMFORTER BED COVERING

Filed Aug. 22, 1949

3 Sheets-Sheet 1



INVENTOR

Nathaniel B. Wales Jr

June 17, 1952

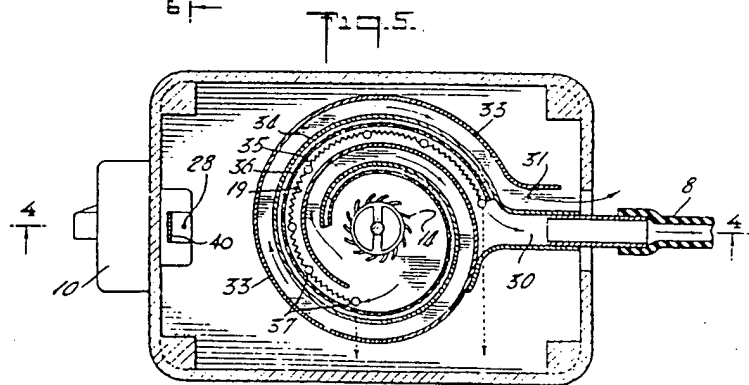
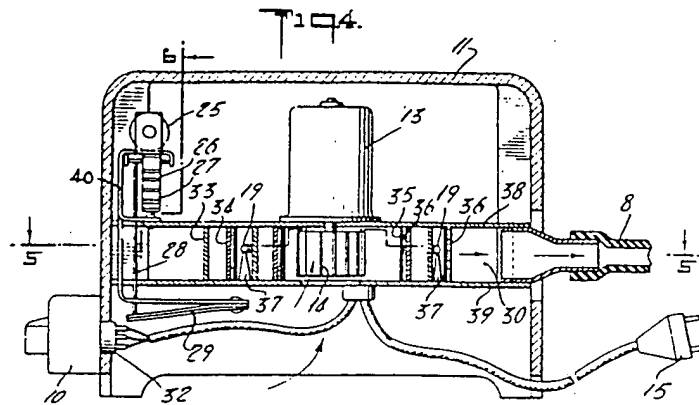
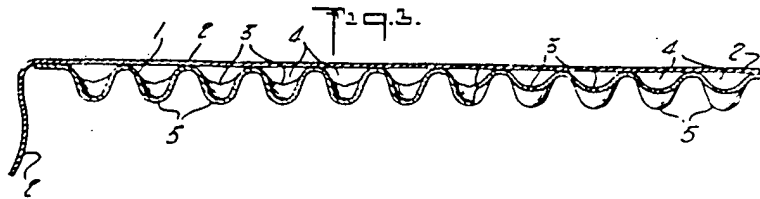
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3 Sheets-Sheet 2



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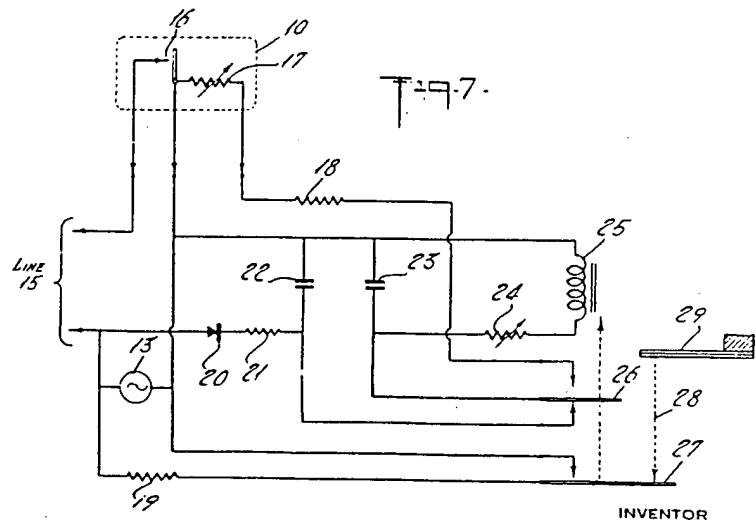
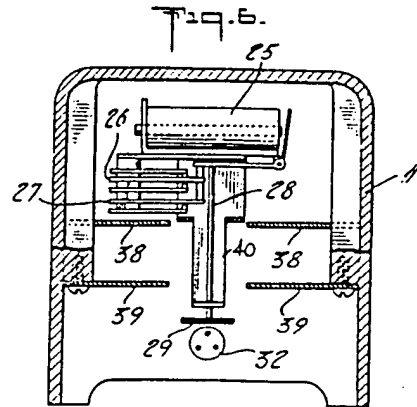
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Filed Aug. 22, 1949

3 Sheets-Sheet 3



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2,601,189

AIR COMFORTER BED COVERING

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Application August 22, 1949, Serial No. 111,647

8 Claims. (Cl. 4-160)

1 This invention relates to a device for delivering fresh or tempered air to the sleeping human body, and to automatic means for providing and regulating such tempered delivery of air.

By means of a program of research in the prior art of air conditioning beds, and of experimentation with such devices, it has been found that the inflatable type of bed covering or air delivery device, which appears in the prior art, suffers from two practical difficulties which have prevented such devices heretofore from being offered on the market. The first of these objectionable features is that in order to maintain distribution channels by inflation, an appreciable air pressure is necessary. This may be provided either by a highly constricted system of delivery apertures, such as that provided by an infrequently perforated inflatable duct using a moderate volume of air delivery, or by a minimized constriction system, such as that offered by a highly perforate inflatable sheeting requiring a correspondingly large rate of air volume delivery, to maintain inflation pressure. The first case results in the delivery to the body of many high velocity minute jets of air with a consequently unhealthful and uncomfortable localized chilling action, whereas this second case, involving both high pressure and high volume of delivery, necessarily requires an excessive amount of blower power, and in addition introduces difficult noise problems, since this class of device must be virtually noiseless.

The second objectionable characteristic of the inflatable type of covering has been found to be its formation of "hot spots" where it contacts the body due to its natural tendency to conform to the body. At these areas of contact, circulation of the air is inhibited, and the consequent temperature gradients are uncomfortable.

The present invention obviates these difficulties by its concept of the combination in a bed covering, of a flexible self-sustaining non-inflated duct delivery manifold with a grid of closely spaced support points on its underside to provide homogeneous accessibility to the covered body of the delivered air.

Because of the fact that this labyrinth of distribution ducts is self-sustaining, although light and flexible, it requires only a fraction of the air delivery pressure which an inflatable duct would require. This permits the use of a small low powered blower unit to diffuse the tempered air at low pressure uniformly over the body, since the duct structure taught by this invention combines self-sustaining air delivery channels with flexibility, light weight, and a geometry guaranteeing an absence of air-obscured areas on the sleeper.

It has been found that this self-sustaining flexible distribution labyrinth may be formed by subjecting a thin sponge composition sheet, such as

2 of foam rubber or plastic, to pressure under appropriate temperatures in a roll press or molding die. The desired geometry provides longitudinal self-sustaining air channels with a grid of supporting fingers or bumps directed downward so as to prevent any appreciable area of the body on which it may bear, either directly or through an intervening sheet, from being made inaccessible of the air delivery to the covering.

In a preferred form of this flexible air delivery manifold, the formed sponge rubber or plastic covering above described is perforated at intervals along the air delivery channels in such a way as to insure uniform air delivery over the area of the covering, and a thin flexible air-imperious sheet is secured to the top of the corrugated sponge composition air channels to comprise self-sustaining air ducts. Thus, in this preferred form of dry air comforter, the upper wall of the ducts is formed by the air impermeous sheet, while the lower walls of the ducts are formed by the molded sponge composition under-covering. This composite manifold may be fabricated in such a way as to be extremely light and flexible.

Evidently, the flexible self-sustaining manifold principle embodying my concept of a grid of support points may be fabricated in a variety of ways and with various materials, such as by an extrusion wholly containing the self-supporting air ducts made of a plastic foam. A second alternative execution of this combination may be effected by joining one impermeous sheet at a grid of points with a perforate sheet by means of multiple closely positioned spacers so as to provide the self-sustaining duct feature in combination with multiple under surface support points.

It is further possible for this purpose to secure a plurality of mutually interconnected individual perforated tubular ducts to a flexible luminant backing sheet to achieve the same end of self-sustaining flexible air delivery during having a dispersed support geometry.

The air comforter embodied in this invention is intended to provide sleeping comfort all year round. To attain this, it has been recognized that the principal source of discomfort in hot weather is the humidity, rather than the temperature, since an excessive humidity causes the human body's natural refrigeration mechanism of surface evaporation of its perspiration, to become ineffective due to the opposing vapor pressure of the air. This invention teaches the use of a drying agent, such as silica-gel to partially remove the moisture from the air delivered to this duct of bed covering. Since such drying agents are generally exothermic in action, this invention further discloses a heat interchange structure which utilizes a portion of the air delivered by the blower to reduce the temperature of the air thus dried

and heated to a temperature closer to the ambient room temperature, thereby providing a further natural and healthful source of body refrigeration.

The air delivery unit shown in this invention is provided with air heating means, for winter use, regulated by a novel form of thermostatically responsive control device. In addition, a separable manual control box is disclosed to constructed that after the initial period of personal adjustment has been passed, the control box, together with its registration of personal selection thus established within it, may be disconnected from its cable, and plugged directly into the air delivery unit, thereby obviating further inconvenience due to the presence of this cable.

An object of this invention is to provide a structure of air-distributing bed covering which will not be contingent on air pressure or the sleeper's movement or position to insure uniform diffusion of air over the area of the bed.

A second object is to make possible the healthful comfort of a sleeper in hot weather without the use of chilled air.

A third object is to make possible the manufacture of an automatic year round air comforter bed covering at a minimum of cost, and at a maximum of quiet and comfort.

Other objects are implicit in the following specification and claims.

Referring to the drawings:

Figure 1 is a view in elevation of a bed showing the disposition of the air delivery and tempering unit, the separable manual control box, and a view in section of the preferred form of my self-sustaining air delivery manifold.

Figure 2 is the plan view of Figure 1 showing the bed covering in partial section along the broken line 2-2 of Figure 1.

Figure 3 is the section 3-3 of Figure 1.

Figure 4 is a section in elevation of the air delivery unit 4-4 of Figure 1.

Figure 5 is the plan section 5-5 of Figure 4.

Figure 6 is the section 6-6 of Figure 4; and Figure 7 is a schematic wiring diagram of the control system of a preferred form of my invention.

The bed covering detailed in Figures 1, 2 and 3 consists of an upper flexible air-impervious sheet 2 which is secured to the periphery and to the longitudinal lines of contact which it makes with the under flexible corrugated and preformed duct member 1. The means of this secureance may comprise cementing, riveting, sewing, or, in the case of plastic materials, thermal bonding. The duct member 1 may be made of sponge rubber or of plastic foam. It is provided with a system of perforations 3, and is so formed as to present a grid of support protuberances 5 on its under side. The longitudinal duct passages 4 are formed in the space between the upper impervious sheet 2 and the longitudinal corrugations formed in member 1. It may be seen in Figure 3 that the protuberances 5 depend from the duct passages 4 and that the air delivery holes 3 are located in the less protuberant lower boundaries of the ducts so as to permit free diffusion of the delivered air over the sleeping body covered by this perforate member 1. An essential feature of this construction is its provision of an air delivery manifold which need not be inflated to form its passages. Thus the self-sustaining nature of these passages will not be closed off or strangled by the creasing, folding, and bodily obstructions, such as by the

weight of an arm or leg, which is suffered by any ducting system dependent on air for its inflation.

The longitudinal air delivery ducts 4 are shown in Figures 1 and 2 all to communicate with the common transverse manifold duct 9 at the foot of the bed covering. Distribution duct 9 in turn is connected by the flexible coupling duct 8 through a suitable separable connector. Duct 8 provides the means for delivery of tempered air from the blower unit 11 to the bed covering, shown resting on the bedding 1 of bed 6. In Figure 1 the separable manual control box 10 is shown in full line plugged into the blower unit 11. The broken line outline 10 shows this control box in its alternative bedside position when connected to the blower unit through cable 12. As shown at the left at Figure 3 the upper impervious sheet 2 is provided with sufficient excess area beyond its secureance to duct member 1 to form a skirt which hangs over the edge of the bed, or may be tucked in under bedding 1, so as to confine the entrance of air underneath the bed covering to the tempered air delivered at low pressure by the blower unit 11.

The blower and tempering unit shown in Figures 4, 5 and 6, comprises a case 11 sustaining an upper (preferably metal) chassis plate 39 and a lower chassis plate 38. These are spaced apart by and secured to the spiral sheet metal walls 33 and 34 so as to form a main air delivery and drying duct 30, and a heat exchanger duct 31. A blower rotor 14 is positioned at the center of the duct system and is driven by motor 13 secured to upper chassis plate 39. Air enters blower rotor 14 axially through the circular hole in lower chassis plate 39, and is delivered in major part through spiral duct channel 30, thence entering delivery tube 8 for distribution through the bed covering. A smaller portion of the air is passed through duct 31 where it cools the wall 34 thence passing out into the room via the clearance hole in case 11 surrounding exit duct 8. Channel 30 is provided with a chemical drying agent 35 for absorbing moisture from the air passing through this channel. This agent, such as silica-gel, may be of granular form, and is contained between a close meshed screen 35 and the duct wall 34 so as to present a large exposed area to the air passing through duct 30. In addition, due to the spiral geometry, the centrifugal component of the air's motion tends to assure a thorough contact between the air and drying agent so positioned. As before noted the absorption of moisture is accompanied in most drying agents by an exothermic reaction which would tend to heat the agent 35 and with it the delivered air. However, an appreciable portion of the heat so generated is conducted through the wall 34, which is in intimate thermal contact with the drying agent, and this heat is carried off by the portion of the air blast delivered by the blower through duct 31. This results in an ultimate net refrigerative effect on the person to whom the air is delivered. An electric air heating element 19 is positioned in duct 30 and is supported on stand off insulators 37 secured to the lower plate 38. This heater wire 19 is energized periodically in cold weather at a rate and pulse length of which the integrated power dissipation is made to be a function of the room's ambient temperature as measured by bimetallic thermoresponsive element 29. It is esti-

dent that by switch means obvious to the art, heater 19 may be continuously energized for a period during the day so as to regenerate the drying agent 36 by baking out the moisture absorbed during the night. Bimetallic element 25 is mounted on a bracket 40 secured to upper chassis 38, the relay 25 carrying leaf switches 26 and 27 is also mounted on bracket 40. A push rod 28 so connects the end of bimetallic leaf 29 and the armature of relay 25 that the resiliency of leaf 29 and the force generated by thermal stresses therein causes this leaf to act as the bias spring for the armature of relay 25. This thermally variable mechanical bias on relay 25 is utilized to control the effective dissipation of heater 19 as may be seen with reference to Figure 7. In Figure 7 a master control switch 16, located in the separable box 10, applies the line current from terminals 15 to the blower 13 and to the heater element 19 through normally open relay contacts 27. In addition, this line voltage is rectified by dry rectifier 20 and applied through limiting resistor 21 to capacitance 22 thereby making 22 a source of direct current. In the energized position of the relay contacts 26, condenser 23 is placed in parallel with condenser 22. Consequently as the potential in condenser 22 rises at a rate influenced by the limiting resistors 21 and the line voltage, the potential rises in parallel condenser 23. Coincidentally the current through the field of relay 25 will also rise in a measure influenced by its own resistance and that of series resistor 24. When the voltage in condenser 23 has risen sufficiently to cause the relay armature to "drop in," relay switch 26 will disconnect condenser 23 from its current supply and connect it to the series shorting resistors 18 and 17. Consequently, the length of time necessary for the relay current derivative from condenser 23 to fall to the "drop out" value will be influenced by the setting of control 17 located in the manual control box.

However, as before outlined, the mechanical bias on the relay 25 is controlled by the ambient temperature of bimetallic strip 29, and, consequently, the period of pulsation of the relay 25 and hence the integrated power output of heater 19 is dependent on the room temperature. Conversely, the pulse length is controllable manually by resistor 17 and so can also modulate the effective wattage of the air heater 19. Due to the appreciably different values of relay current for "drop in" and "drop out" for a given mechanical bias it has been found that the system may be easily made to operate over a 20 to 1 range of integrated power dissipation. By proper choice of components and adjustment of resistor 24 the system is caused to deliver no current to the heater 19 above any chosen "cross over" temperature. Consequently, with dropping temperature, the mechanical bias supplied by strip 29 diminishes until the relay can begin pulsing, thereby delivering increasing power to the heater as the rate of pulsing increases.

What I desire to protect by United States Letters Patent is encompassed in the following claims:

1. In a bed covering, the combination comprising an air-imperious flexible upper cover member, a flexible perforated lower distribution member secured at its periphery to said upper cover member, means for forming a plurality of self-sustaining air distribution ducts between said upper cover member and said lower per-

forated member, said ducts being in communication with the perforations in said lower member, a source of air pressure, and duct means communicating between said source of air pressure and said self-sustaining ducts whereby to diffuse air downwardly through the perforations in said lower distribution member.

2. In a bed covering, the combination comprising an air-imperious flexible upper cover member, a flexible lower distribution member secured to said upper cover member, means to space intermittently said upper cover member from said lower distribution member between the points of said secureance whereby to form a manifold of self-sustaining air distribution ducts therebetween, said spacing means forming an array of protuberant support areas in said lower distribution member, a plurality of perforations in said lower distribution member communicating with said self-sustaining ducts, a source of air pressure, and flexible duct means communicating between said source of air pressure and said self-sustaining ducts whereby to diffuse air downwardly from said bed covering through said perforations.

3. In a bed covering, the combination comprising an air-imperious flexible upper cover member, a flexible perforated lower distribution member, a plurality of self-sustaining air distribution ducts interposed between said impervious upper member and said perforated lower member and communicating with the perforations in said lower member, a plurality of protuberant support areas formed in said lower member, a source of air pressure, and flexible duct means communicating between said source of air pressure and said self-sustaining distribution ducts whereby to diffuse air downwardly from said bed covering through said perforations.

4. In a bed covering according to claim 9, means for heating the air passing through said flexible duct means.

5. In a bed covering according to claim 9, air-drying means for drying the air passing through said flexible duct means.

6. In a device for diffusing air from a bed covering, the combination comprising a flexible self-sustaining air distribution manifold integral with said bed covering, means to diffuse air delivered by said manifold downwardly from said bed covering, an air pump, an exothermic agent for absorbing moisture from said air, heat-exchanger means for lowering the temperature of the air heated by said exothermic agent, a first duct means for conveying a portion of the air displaced by said pump first into contact with said exothermic drying agent and then into said distribution manifold for diffusion through the bed covering, and a second duct means for conveying a remaining portion of the air displaced by said pump into contact with said heat-exchanger means.

NATHANIEL B. WALES, JR.

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April 26, 1955

H. WEBER

2,706,988

HUMAN BODY HEAT TREATING APPARATUS

Filed Sept. 15, 1952

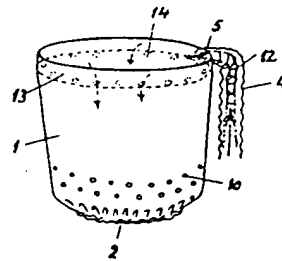
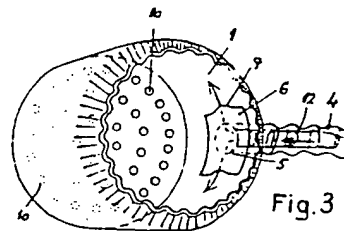
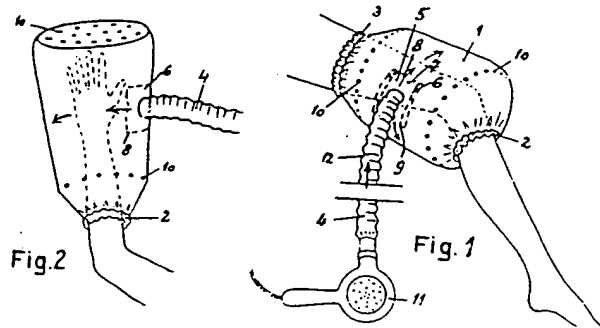


Fig. 4

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2,706,988

HUMAN BODY HEAT TREATING APPARATUS

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Application September 15, 1952, Serial No. 309,660

Claims priority, application Switzerland
November 19, 1951

4 Claims. (Cl. 128—402)

The instant invention relates to apparatus for heat treating portions of the human body of the type adapted to be connected to a source of heated air.

An object of the invention is to provide heat treating apparatus into which portions of the human body may readily be inserted and enclosed for curative heat treatment or for drying the enclosed limb, organ or hair, for example.

A further object of the invention is to provide heat treating apparatus which may readily be sealed at one or two end regions thereof adjacent to the body portions being treated with heated air, and into which heated air is then admitted and given such direction within the apparatus that the heated air circulates about the body portion being treated rather than striking it directly.

Still a further object of the invention is to provide a heat treating apparatus having means to deflect the incoming heated air in such manner that the air is circulated along the interior surface region of the apparatus wall.

I accomplish the foregoing and other objects, by providing a pliable casing open at one end, or at two opposite ends thereof, each open end having elastic means to seal off such end to the body portion adjacent the body portion being treated, with a radially extending inlet pipe substantially away from the open end, respectively ends, and beyond and adjacent to the inlet pipe internally the apparatus disposing a deflecting member adapted to intercept the radially incoming heated air and imparting thereto a substantially tangential flow about the inner surface of the apparatus. In an alternative form, the deflecting means comprises a transverse wall near one end of the apparatus between which and the closed end of the apparatus the heated air is admitted, and a plurality of ports disposed adjacent the periphery of the transverse wall directs the heated air longitudinally along the region adjacent the inner surface of the apparatus wall.

The invention will be readily understood from the following description of several illustrative embodiments thereof in conjunction with the appended drawings in which:

Figure 1 shows a first embodiment of my apparatus of the two open end type adapted for the treatment of an intermediate portion of a human limb, such as a leg or arm member;

Figure 2 shows a second embodiment for the treatment of an end portion of a human limb, such as a hand or foot, or for drying hair;

Figure 3 shows a modification of the shape of the second embodiment suitable particularly for drying hair and shows the deflecting means thereof from internally the apparatus; and

Figure 4 shows a third embodiment thereof in which the deflecting means is a transverse dividing wall.

Like reference characters in the various figures of the drawing identify like parts of the illustrative embodiments. Referring to the first embodiment of Figure 1, the casing 1 is of a tubular form and made of a flexible, supple material substantially impervious to air. Openings 2 and 3, at the respective ends of the tubular casing 1, permit the passage of a limb therethrough, and are formed of a suitable elastic yielding material, preferably one that does not lose its elasticity with repeated subsection to heated air, to seal the ends of casing 1 to the limb. A flexible air pipe 4 opens into the interior of casing 1 substantially radially to form the port 5 over which

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extends a deflecting member 6, also of flexible supple material impervious to air preferably, affixed to the inner surface of the casing adjacent to port 5 and having a central inwardly spaced loose portion 7 which form a tangentially extending duct, 8 and 9, with the inner surface of the casing 1, to opposite sides of the port 5 and deflects air along the inner surface region of the casing as shown by the arrows. If desired, and to produce a powerful unidirectional circumferential blast of all the heated air admitted through the air pipe 4, one of the ducts may be closed so that all the heated air admitted must pass through the one open duct. At a region removed from port 5, a plurality of air outlet apertures 10 permits the air to escape after having circulated about the limb portion under treatment. The sum total of the areas of the apertures 10 is such that upon admission of heated air into the casing 1 from air inlet pipe 4 connected to any convenient source of heated air, such as the hot air blower 11, the casing will be inflated and remain inflated as long as heated air is being supplied. To assure continuous flow of heated air through the flexible pipe 4, a stiffening member such as the wire spiral 12, is incorporated in the walls of the pipe to keep it open and dilated, as also to minimize breakage thereof. Obviously instead of the hot air blower 11 shown, any source of hot air currents may be used, for example, the compression side of a vacuum cleaner may be connected to pipe 4 through the intermediary of a heating element.

The other illustrative embodiments of Figures 2 to 4 differ from the first embodiment in that the casing 1 in Figure 2 is in the shape of a sack, while in Figures 3 and 4 it is in the shape of a cup, and in all these other embodiments only one end 2 is open and elastically yielding to seal the one end to the limb being heat treated, respectively the head while drying the hair. In the embodiments of Figures 2 and 3 the air outlets 10 are disposed in the closed casing end opposite open end 2, while in Figure 4 they are in the wall of casing 1 relatively adjacent open end 2. The sack shape of Figure 2 is preferable for the treatment of extremity limbs, such as a hand as shown, while the cap shape of Figures 3 and 4 is preferable for drying hair.

In the third embodiment of Figure 4, casing 1 is in the form of a bag, or cap as stated, with but one open end 2, which is elastically yielding as in the other embodiments to seal the open end to the inserted limb or body portion. The air pipe 4 opens into the casing in the region thereof remote from the open end 2 and between the closed end and a dividing wall extending transversely the bag to form a separate compartment. Adjacent the peripheral portion of dividing wall 13, a plurality of apertures 14 directs the air from the upper (as shown in Figure 4) compartment into which it is supplied through port 5 from the air pipe 4, downwardly along the region adjacent the inner surface of the casing 1. It will be noted that in this embodiment, likewise, the heated air is not directed against the body portion being heat treated but across it as in the other embodiments albeit longitudinally the surface rather than circumferentially as in the other embodiments. The plurality of heated air venting apertures 10 is positioned adjacent the open end 2 in this embodiment.

Various obvious modifications will suggest themselves to the skilled worker in the art without departing from the spirit of the instant invention as defined by the claims.

What I claim is:

1. Heat treating apparatus for the heat treatment of portions of the human body comprising a pliable casing impermeable to air, a resilient opening adapted to fit closely to a portion of the human body adjacent the portion to be treated in at least one end of the casing, an air inlet port at a region of the casing remote from the resilient opening, a flexible substantially non-collapsible pipe connected to the inlet port and adapted to pass heated air from a source into the casing, and deflecting means of material impermeable to air cooperating with the port to direct heated air admitted through the port along the region within the casing adjacent the inner surface of the casing.

2. Heat treating apparatus according to claim 1 in which the deflecting means is supported by the inner sur-

face of the casing adjacent the port and is spaced from the port at its portion immediately registering with and adjacent to the port to form with the adjacent region of the casing a nozzle directing the admitted heated air circumferentially in at least one direction along the surface of the casing.

3. Heat treating apparatus according to claim 1 in which the deflecting means comprises a pocket of flexible material impervious to air having a loose central portion between two edge regions attached to the casing regions adjacent the port, the loose central portion of the pocket forming with the casing region registering therewith a pair of oppositely directed orifices directing the heated air admitted through the port circumferentially along the interior surface of the casing in two streams oppositely directed.

4. Heat treating apparatus for the heat treatment of portions of the human body comprising a pliable casing impermeable to air, a resilient opening adapted to fit closely to a portion of the human body adjacent the portion to be treated in at least one end of the casing, an air inlet port at a region of the casing spaced from the resilient opening, a flexible substantially noncollapsible pipe connected to the inlet port and adapted to pass heated air from a source into the casing, a substantially quadrangular

strip of air impervious material attached to the interior of the casing and disposed over the inlet port, the attachment being in at least two opposite strip end regions and the spacing between opposite attachments on the cylinder being at least equal to the dimension of the inlet port parallel thereto but less than the parallel dimension of the strip between such opposite attachments so that the strip region between the attachments may be displaced away from the inner surface of the casing or passage of air through the inlet port into the casing, the displaceable portion of the strip forming with the registering casing region a pair of oppositely directed orifices directing the admitted air circumferentially along the interior surface of the casing in two oppositely directed streams, and a plurality of air outlet apertures in the casing relatively remote from the air inlet port.

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Dec. 31, 1968

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3,418,726

HAIR DRYER

Filed Dec. 19, 1966

FIG. 1.

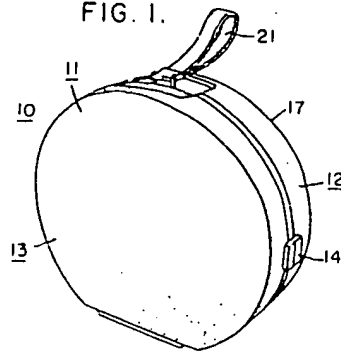


FIG. 2.

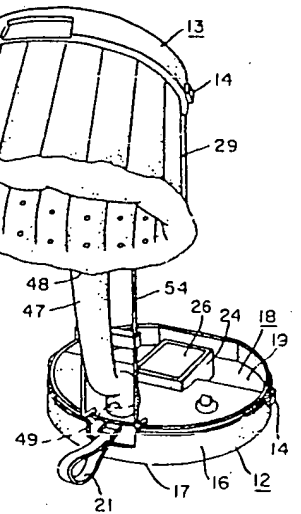


FIG. 3.

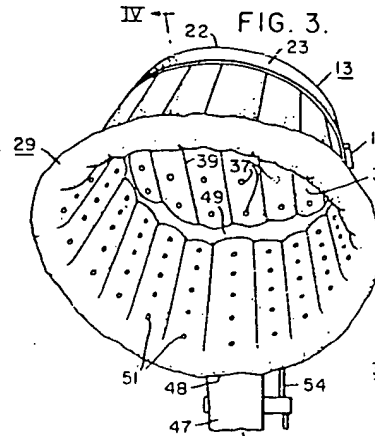


FIG. 4.

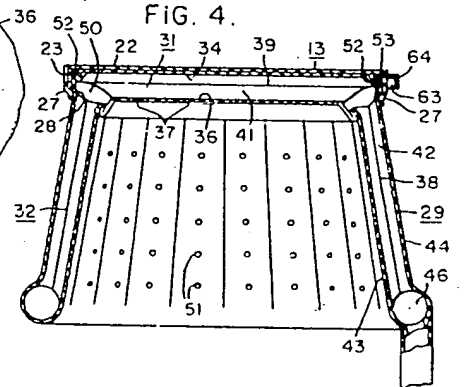


FIG. 5.

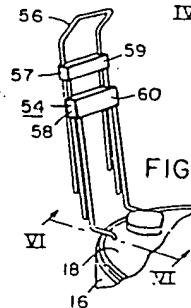
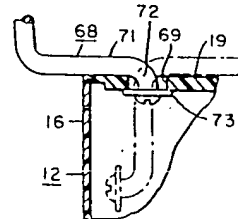


FIG. 6.



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3,418,726
HAIR DRYER
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Filed Dec. 19, 1966, Ser. No. 602,883
10 Claims. (Cl. 34-99)

ABSTRACT OF THE DISCLOSURE

A portable hair dryer having an inflatable hood and a support structure therefor which enables it to be used like a salon type unit by slipping the head into and out of the hood. When inflated the side walls of the hood stand away from each other to form a salon type hood which when collapsed packs neatly into a compact carrying case provided therefor.

This invention relates, in general, to portable hair dryers and, more particularly, to portable salon-type hair dryers.

Wholehearted acceptance of portable hair dryers dictates that they be efficient in operation, compact in size, easy to operate and afford an optimum degree of comfort during use.

One model hair dryer currently available to the consumer is fashioned after the professional or commercial salon-type unit in that it has a rigid hood or bonnet which is supported on a stand to enable the user to sit thereunder. The hood is also utilized as a combination cover, for the power unit, and carrying case. Of all available portable hair dryers, this type is probably the most efficient and least objectionable from the standpoint of discomfort during use, however, it lacks compactness and because of its inflexibility restricts movement of the head. In other words, the head must be moved about carefully within the hood to avoid bumping of the rigidly constructed walls thereof.

The bonnet type hair dryers overcome some of the objectionable features of the portable salon-like dryer. For example, they possess the desirable features of compactness and flexible walled construction. However, they are less efficient in operation due to poor air circulation, moreover, they cause discomfort due to impressions on the forehead and pressure exerted on the ears by the elastic band or drawstring used for snugly fitting the bonnet on the head.

From the standpoint of operation, it is desirable to have a minimum number of operations to perform in order to ready the hair dryer for use. Most portable hair dryers are cumbersome in this respect.

Accordingly, it is the general object of this invention to provide a new and improved portable hair dryer.

It is a more particular object of this invention to provide a new and improved bonnet for a portable hair dryer.

Another object of this invention is to provide a new and improved bonnet type hair dryer which is compact in size yet highly efficient in operation.

Still another object of this invention is to provide a new and improved portable hair dryer which is easy to operate.

Yet another object of this invention is to provide, in a salon-type portable hair dryer, an inflatable flexible walled hood.

Briefly, the above-cited objects are accomplished by

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providing a hair dryer comprising a hood made from flexible vinyl plastic or other suitable material and adapted to be inflated. The hood is attached to the cover of a relatively shallow carrying case which cover serves as a storage receptacle for the hood when not in use. This is accomplished by collapsing or folding the flexible hood into the cover. The cover is provided with one part of a support structure which is adapted to receive the free end of a stand supported by the base of the carrying case. Accordingly, the base of the carrying case which houses the power means may be placed on a table such that the user can place her head into and out of the flexible bonnet which depends like an annular curtain from the carrying case cover. Since the bonnet is inflatable, it assumes a shape similar to that of a professional salon type hair dryer.

The foregoing and other objects of the present invention will become more apparent when considered in view of the following detailed description and drawings, in which:

FIGURE 1 is a perspective view of a hair dryer, in a knocked-down condition, representing the invention;

FIG. 2 is an assembled perspective view of the hair dryer illustrated in FIG. 1;

FIG. 3 is a perspective view of the bonnet portion of the hair dryer shown in FIG. 2;

FIG. 4 is a cross-sectional view taken on the line IV-IV of FIG. 3;

FIG. 5 is an enlarged fragmentary perspective view illustrating a support structure forming a part of the present invention; and

FIG. 6 is a cross-sectional view taken on the line VI-VI of FIG. 5.

Referring now to the drawings, especially FIG. 1, reference character 10 indicates generally a portable hair dryer comprising a carrying case 11 including a base 12 and a cover 13. The cover and base are provided component parts of a pair of latch or lock mechanisms 14 (only one of which is shown) for securing the cover 13 to the base 12 such that the cover can be completely detached therefrom as shown in FIG. 2.

The base 12 comprises a vertical annular wall 16 formed integrally with a generally circular bottom wall 17. A generally horizontal partition 18 serves as a closure for the base 12 in which power apparatus, not shown, is contained. The partition 18 is recessed or dished as at 19 to provide a storage area for a power cord, not shown. The partition 18 is also provided with an air intake 24 which carries an air filter 26. A strap 21 attached to the wall 16 of the base 12 provides means for readily carrying the dryer 10.

The cover 13 comprises a top wall 22 (see FIG. 4) formed integrally with a vertical annular wall 23 having a peripheral flange 27 with a reversed lip construction including an inwardly protruding portion 28.

The hair dryer 10 includes an integral hood structure 29 made from any suitable material, for example, flexible vinyl plastic. The hood 29 comprises a top wall structure 31 having a generally circular configuration and an annular, depending or side wall structure 32. The top wall or crown structure 31 consists of an imperforate top wall 34 and a bottom wall 36 provided with a plurality of apertures 37. The walls 34 and 36 are joined, as by heat welding, along lines indicated at 39 (see FIG. 4) to thereby form a plurality of generally horizontal air distributing channels 41 to which air is conveyed (in a

manner to be more fully described hereinafter) from substantially vertical air channels 42 formed in the annular depending wall structure 32 by heat welding along the lines indicated at 38.

The wall structure 32 consists of a generally cylindrical inner wall 43 and a generally cylindrical outer wall 44 which are joined together at the bottom edges, also by heat welding. The heat welds at 38 terminate at approximately $2\frac{1}{2}$ " from the lower edge of the wall structure 32 thereby providing an annular air duct 46 communicating with the vertical channels 42 to provide communication between a flexible coupling conduit 47 and the latter. One end of the conduit 47 is heat welded to the wall structure 32 as indicated at 48 (see FIGS. 2 and 4) while the other end is coupled to an air outlet 49 (shown in dotted lines in FIG. 2) provided in the partition 18 and which communicates with the power means, not shown.

The periphery of the imperforate top wall 34 is joined to the periphery of the outer wall 44 and the bottom wall 36 is joined to the inner wall 43 to form the integral bonnet structure 29 (see FIG. 4). The heat welds along the lines 39 terminate at approximately one inch from the top of the wall structure 32 and the welds along the lines 38 terminate at points remote from the peripheral edge of the top wall structure 31 thereby forming a second annular air channel 49 at the jointure of the walls 34 and 36 with the walls 44 and 43, respectively. It is this channel 49 which provides the communication between the vertical channels 42 and the horizontal air channels 41. Air flowing in the channels 41 is distributed over the top head of the user through the exhaust apertures 37. Similarly air flowing through the vertical channels 42 is distributed over the sides, front and back of the head through exhaust apertures 51 and in the inner wall 43.

A flexible cylindrical band 52 (see FIG. 4) attached in any suitable manner, as by gluing to outer wall 44 at the top thereof, is insertable in a continuous groove 53 formed between the top wall 22 and the inwardly projecting portion of the peripheral flange 27, the band 52 being captivated therein by the inwardly projecting portion 28.

In this manner the bonnet 29 is adapted to be supported for use by the cover 13 which is, in turn, carried by an extensible or telescopic stand or support structure 54 (best shown in FIG. 5).

The support structure 54 comprises U-shaped rods 56, 57 and 58 coupled together by connecting members 59 and 60. Each of the U-shaped members 57 and 58 has a straight bight portion which is insertable in slots in the undersides of connecting members 59 and 60. The bight portion of the U-shaped rod 56 is insertable in a slot 63 (see FIG. 4) formed by a portion of the annular wall 16 and a complementary part 64 suitably secured thereto. The bight portion of the rod 56 is slightly offset from the legs thereof in order to provide the proper angle of inclination of the cover 13 and, consequently, the bonnet 29 when the cover is mounted thereon.

The legs of the U-shaped rods 56 and 57 are slidable within elongated bores 66 and 67 provided in the connecting members 59 and 60 to permit variation of the height of the bonnet. The legs of the U-shaped rod 58 are offset as indicated at 68 (see FIG. 6) and are inserted through apertures 69 in the partition 18 such that the legs of the offset segments 68 move freely therethrough for permitting the supporting structure 54 to be folded flat for storage on top of the partition 18. Each of the offset segments 68 includes two legs 71 and 72, the latter of which is provided with an outwardly projecting flange 73, in the form of a washer captivated by a screw 74, which cooperates with the underside of the partition 18 to retain the support structure in the operating position.

Since numerous changes may be made in the above described apparatus and different embodiments of the invention may be made without departing from the spirit thereof, it is intended that all matter contained in the

foregoing description or shown in the accompanying Drawings, shall be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. In a portable hair dryer, hood structure comprising: a side wall structure of generally circular cross section including a flexible outer wall and a flexible inner wall, a crown structure including a flexible top wall and a flexible bottom wall each having a generally circular shape, said top wall structure being joined to said side wall structure at one end of the latter, said top and bottom walls being joined at spaced intervals to provide air circulating channels therebetween, said inner and outer walls being joined at spaced intervals to provide air circulating channels therebetween, at least some of said channels in said side wall structure being in communication with some of said channels in said crown structure, means for introducing air into said channels in said side wall structure at the end thereof opposite said crown structure, said bottom and inner walls having apertures communicating with said channels for permitting air in said channels to exhaust therefrom.

2. Structure as specified in claim 1, wherein the top wall is joined to said outer wall and said bottom wall is joined to said inner wall to provide an annular air circulating channel thereat.

3. Structure as specified in claim 1, wherein the air channels in said side wall structure are disposed along the longitudinal axis thereof and the jointure between said inner and outer walls terminate intermediate the ends of said side wall structure and the periphery of said crown structure to thereby provide an annular air circulating channel at the end thereof opposite said crown structure.

4. Hair drying apparatus comprising: a carrying case including a base having an air inlet and outlet and a detachable cover, an inflatable hood, said hood comprising a crown structure and a side wall structure of generally circular cross section joined thereto, each of said structures being provided with air circulating channels and exhaust apertures, said cover having a top wall and an annular wall integral therewith, means for securing said hood adjacent said crown structure to said cover, means carried by said base for supporting said cover above said base whereby said side wall structure depends therefrom for insertion and removal of the head to be dried, said hood being collapsible into said cover for storage thereof in said case and means interconnecting said air outlet means with said hood for conveying air therebetween.

5. Structure as specified in claim 4, wherein said air conveying comprising a flexible conduit and which includes means for permanently attaching said conduit to said outlet and said hood.

6. Structure as specified in claim 4, wherein said support means comprises relatively movable sections whereby said cover may be supported at various levels above said base.

7. Structure as specified in claim 4, wherein said support structure is adapted for movement from an inoperative position wherein it lies substantially parallel to said base to an operative position wherein it is substantially perpendicular to said base.

8. Structure as specified in claim 4, wherein said crown structure comprises a top wall and a flexible bottom wall, said top and bottom walls being joined along lines at spaced intervals to provide air circulating channels therebetween, said side wall structure including an inner wall and an outer wall joined along lines at intervals along the circumference thereof to provide air circulating channels therebetween, at least some of said side wall channels being in communication with said crown channels.

9. Structure as specified in claim 8, wherein said top wall is joined by heat welding to said outer wall and said bottom wall is joined to said inner wall to provide an annular air circulating channel thereat.

10. Structure as specified in claim 9, wherein the side

wall jointures extend along the longitudinal axis of and are disposed intermediate the ends of said side wall structure whereby there is provided an annular air channel adjacent both ends of said side wall structure.

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[31]

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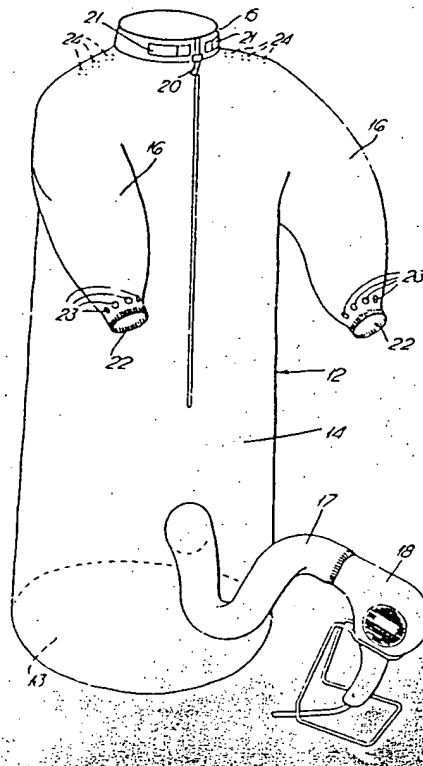
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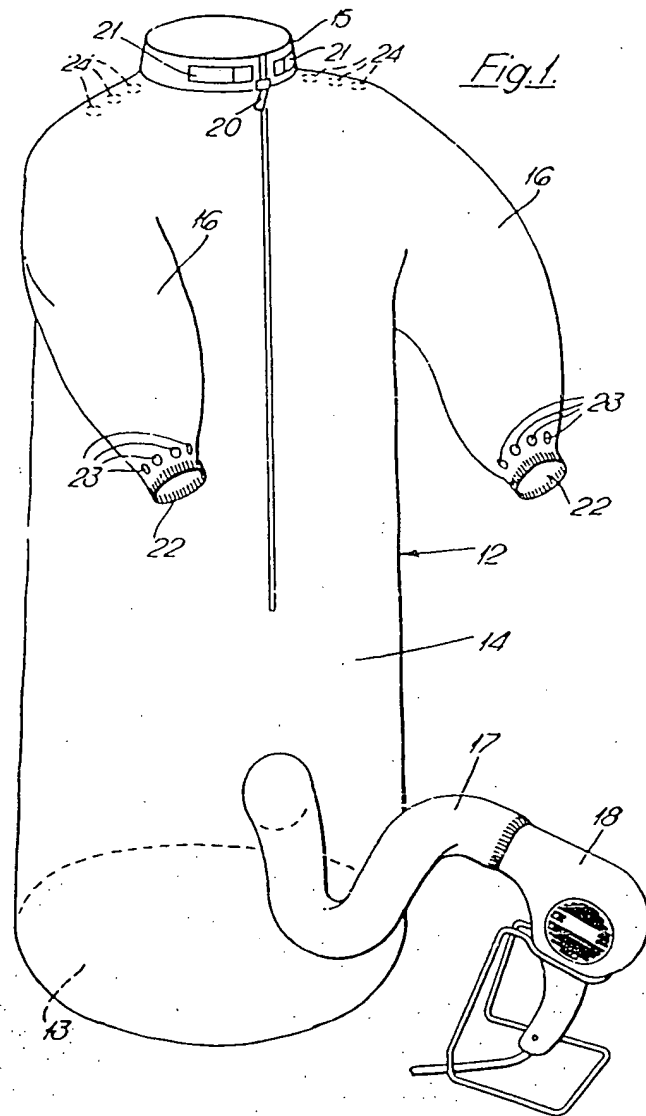
[54] APPLIANCE FOR THE HEAT TREATMENT OF A HUMAN BEING
2 Claims, 2 Drawing Figs.

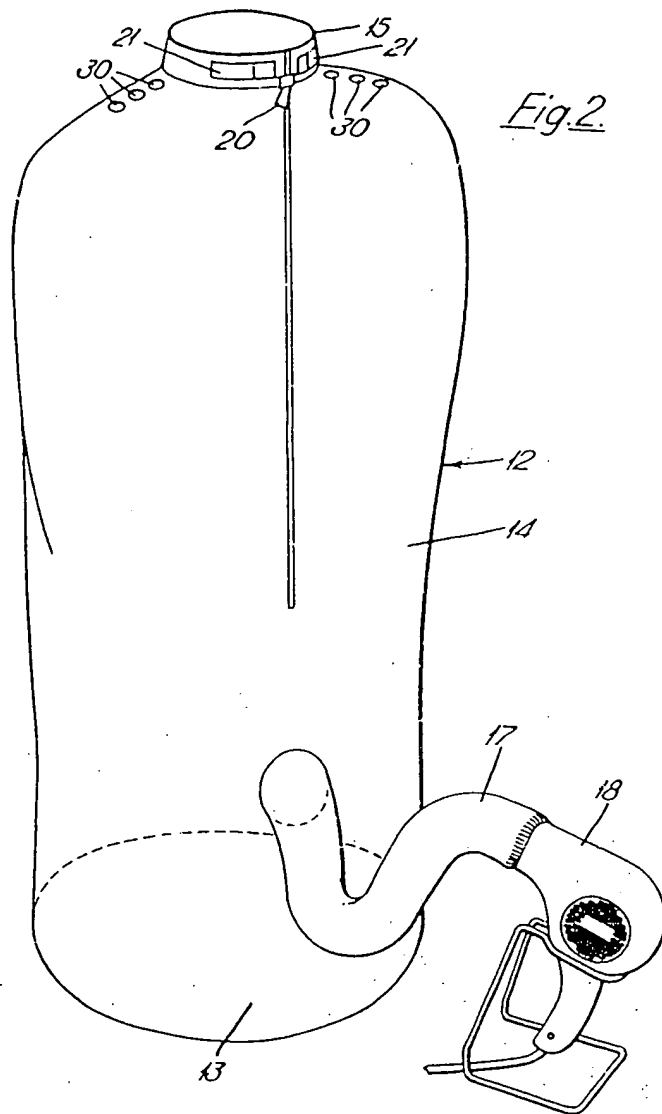
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[51] Int. Cl. A61n/00
[50] Field of Search 2/69.5, 69, 2.1 A, 2.1, 2, DIG. 1; 128/379, 399, 400, 402; 4/164, 165, 160; 165/46; 126/204

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ABSTRACT: An appliance suitable for use in the heat treatment of a human being comprising a loose-fitting, body enveloping, baglike garment of a flexible, nonporous material closed at the bottom end, the other end, which is open, terminating in a neckband, which is preferably adjustable. A conduit is connected to the closed end of the garment for the supply of hot dry air to the interior of the suit. Apertures are punched in the garment in positions remote from the conduit connection for the escape of hot air. The garment may optionally have arms with adjustable cuffs and in which case the apertures are located adjacent the cuffs.







APPLIANCE FOR THE HEAT TREATMENT OF A HUMAN BEING

The present invention relates to an appliance to be worn by a human being and which is suitable for use in heat therapy and for stimulating the physical and psychological effects of a sauna bath.

In a sauna bath a person wholly or partially encases their body and subjects their body to dry heat. This is contrary to a steam or Turkish bath in which the body is subjected to wet heat.

Sauna baths are of such a construction as to render them relatively expensive to manufacture. It is therefore an object of the invention to provide an appliance which simulates to the user the physical and psychological effects of a sauna bath but which is inexpensive to manufacture.

According to a first aspect of the present invention there is provided an appliance suitable for use in the heat treatment of a human being, comprising a baglike garment of a size sufficient to accommodate an adult human being and which is closed at one end, a neckband at the other end, a conduit for connection to a hot air blower communicating with the interior of the garment and a plurality of apertures in the garment remote from the conduit entry.

According to a second aspect of the present invention, there is provided an appliance suitable for use in the heat treatment of a human being, comprising a baglike garment of a size sufficient to accommodate an adult human being and which is closed at one end, a neckband at the other end, two sleeves with adjustable cuffs, a conduit for connection to a hot air blower communicating with the interior of the garment and a plurality of apertures in the garment remote from the conduit entry.

Preferably the neckband is adjustable to suit the neck size of the user.

If desired, the conduit may be connected to the garment at a point adjacent to, but spaced from, the closed end of the garment.

The apertures may be arranged adjacent to, but spaced from, each cuff. Further apertures may be provided between the top of each sleeve and the neckband.

According to a third aspect of the invention there is provided the combination of a hot air blower and an appliance suitable for use in the heat treatment of a human being comprising a baglike garment of a size sufficient to accommodate an adult human being and which is closed at one end, an adjustable neckband at the other end, two sleeves with adjustable cuffs, a conduit for connection to the hot air blower and communicating with the interior of the garment and a plurality of apertures in the garment remote from the conduit entry.

For convenience in the following description the appliance will be referred to as a sauna suit.

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

FIG. 1 is a perspective view of a preferred embodiment of a sauna suit with sleeves; and

FIG. 2 is a perspective view of a sleeveless sauna suit.

In the drawings similar reference numerals have been used to identify similar parts.

Referring to FIG. 1, the sauna suit 12 comprises a baglike garment made from lightweight flexible material such as polyvinylchloride (P.V.C.) or woven nylon fabric backed with rubber or plastics material. The garment comprises a substantially circular base 13 of between 18 and 24 inches in diameter, a barrel-shaped body portion 14, an adjustable neckband 15, sleeve 16 and a flexible conduit 17 communicating with the interior of the body portion 14. The sauna suit 12 is of such a size as to be a very generous fit on the user thereby facilitating the circulation of hot dry air introduced into the suit from a hot air blower 18, e.g. a domestic hair drier, connected to the conduit 17.

A sliding clasp fastener or closure member 20 is fitted into the front of the suit 12 to facilitate the entry by a user into the

suit. The closure member 20 may extend in other directions besides down the front of the suit, for example, along the shoulders or towards the armpit. The size of the neckband 15 is adjustable by means of nylon limpet strips 21 each comprising two parts, one in the form of barbs on a material backing and the second in the form of a strap having a looped or woolly surface which when engaged by the barbs is secured thereto. Alternatively, in a nonillustrated embodiment, the neckband 15 can be elasticated or adjusted in size by means of drawstrings.

The sleeves 16 terminate in cuffs 22 which are elasticated to grip the wrists of the user. A series of circular apertures 23, e.g. eight apertures of about a quarter of an inch in diameter are punched out of each sleeve 16 about five inches from the respective cuff 22. The apertures 23 are provided to facilitate the exit of hot air from the suit after it has circulated through the body portion 14. If desired, further apertures 24, shown in broken lines, may be provided in each shoulder of the suit.

The flexible conduit 17 is preferably made of the same material as the rest of the suit. The free end of the conduit 17 is elasticated to grip the outlet of the hot air blower 18. Typical dimensions of the conduit 17 are that it is 18 inches long and 3 inches in diameter. The connection of the conduit 17 to the body portion 14 is at approximately seven inches from the adjacent edge of the circular base 13.

The preferred mode of using the sauna suit is with the user in a relaxed sitting position in an environment at a temperature of between 65° F. and 70° F.

The user undresses and then enters the suit by unfastening the closure member 20 and climbing in one leg at a time. The arms are passed through the sleeves 16 so that the hands are exposed thereby enabling the user to fasten the closure member 20.

The nylon limpet strips 21 at each side of the neckband 15 are adjusted until the neckband is a tight but comfortable fit on the user's neck.

The conduit 17 is connected to the outlet of the blower 18 which has been placed in a convenient position. Naturally, precautions should be taken to ensure that the conduit is not bent or twisted thereby ensuring that the flow of air is not impeded. The blower 18 is then switched on and the suit is inflated by hot air from the blower. It is desirable from the point of view of user comfort that the temperature of the air at the outlet of the blower should not exceed 200° F.

After a period of at least 30 minutes, and not exceeding 60 minutes, the blower is switched off and the user removes the sauna suit.

Referring to FIG. 2, the illustrated sauna suit 12 differs from that of FIG. 1 by being sleeveless and by having apertures 30 along each shoulder only. With this embodiment it is necessary for a user to be assisted into and out of the suit 12.

In each of the illustrated embodiments by having the apertures remote from the conduit connection, the circulation of hot air over the major part of the user's body is ensured. It is within the scope of the present invention to connect the conduit to another part of the garment and to arrange the apertures so that the hot air follows a path over the major part of the user's body.

It is to be understood that the invention herein is described in specific respects for the purposes of this description. It is also understood that such respects are merely illustrative of the application of the principles of the invention. Other arrangements may be devised by those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. An appliance suitable for use in the heat treatment of a human being, comprising

a. a garment having an elongate tubular body member of single layer, nonporous, flexible material generally cylindrical in shape with a substantially flat bottom thereby providing an unobstructed interior throughout the length of the garment, the lower end of the body member being closed, means defining a neck opening in said garment, a

neckband in said neck opening, means enabling the size of said neckband to be adjustable, an elongate entrance slit extending from said neck opening, fastening means for releasably closing said entrance slit, arm receiving extending outwardly from said body member, cuffs on said sleeves, means enabling the size of the cuffs to be adjustable, means defining unobstructed apertures in said sleeves adjacent to, but spaced from, the cuff on each sleeve, a flexible conduit attached to and communicating with the interior of said body member through an unobstructed

opening, said opening positioned adjacent to, but spaced from, said lower end, and

b. a portable hot air blower connected to said conduit to direct hot air into said body member and out through said apertures.

2. An appliance according to claim 1, further comprising means defining apertures adjacent to, but spaced from, said neckband.

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[54] HYPOTHERMIA BABY BUNTING

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 114,607, Feb. 11, 1971.

[52] U.S. Cl. 128/400

[51] Int. Cl. A61F 7/00

[58] Field of Search 128/400, 402, 1 B, 134, 379, 128/399; 5/343

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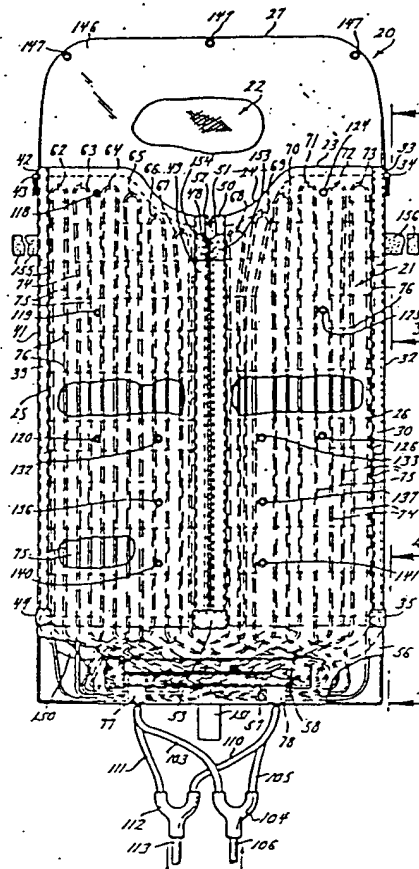
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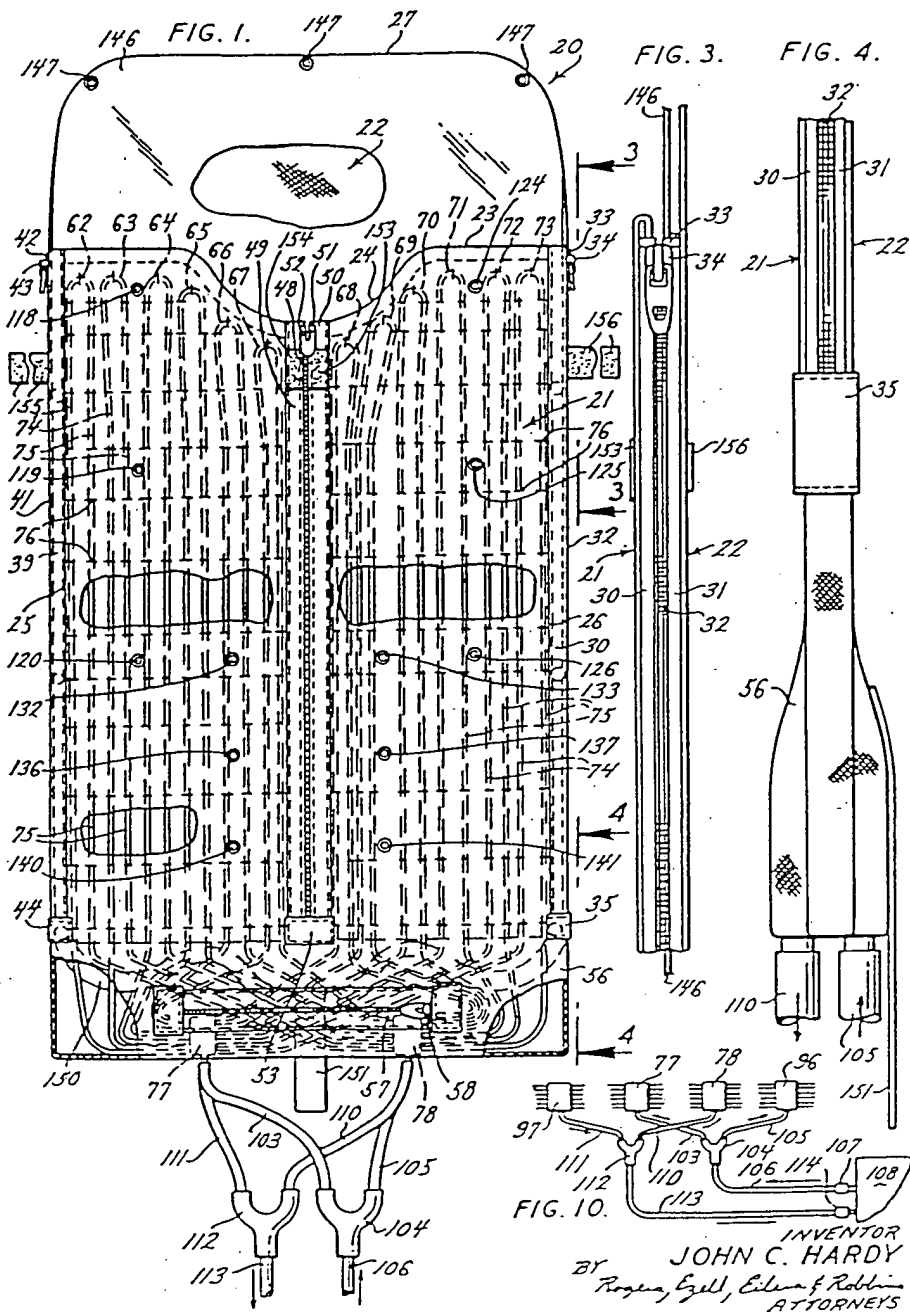
Primary Examiner—Lawrence W. Trapp
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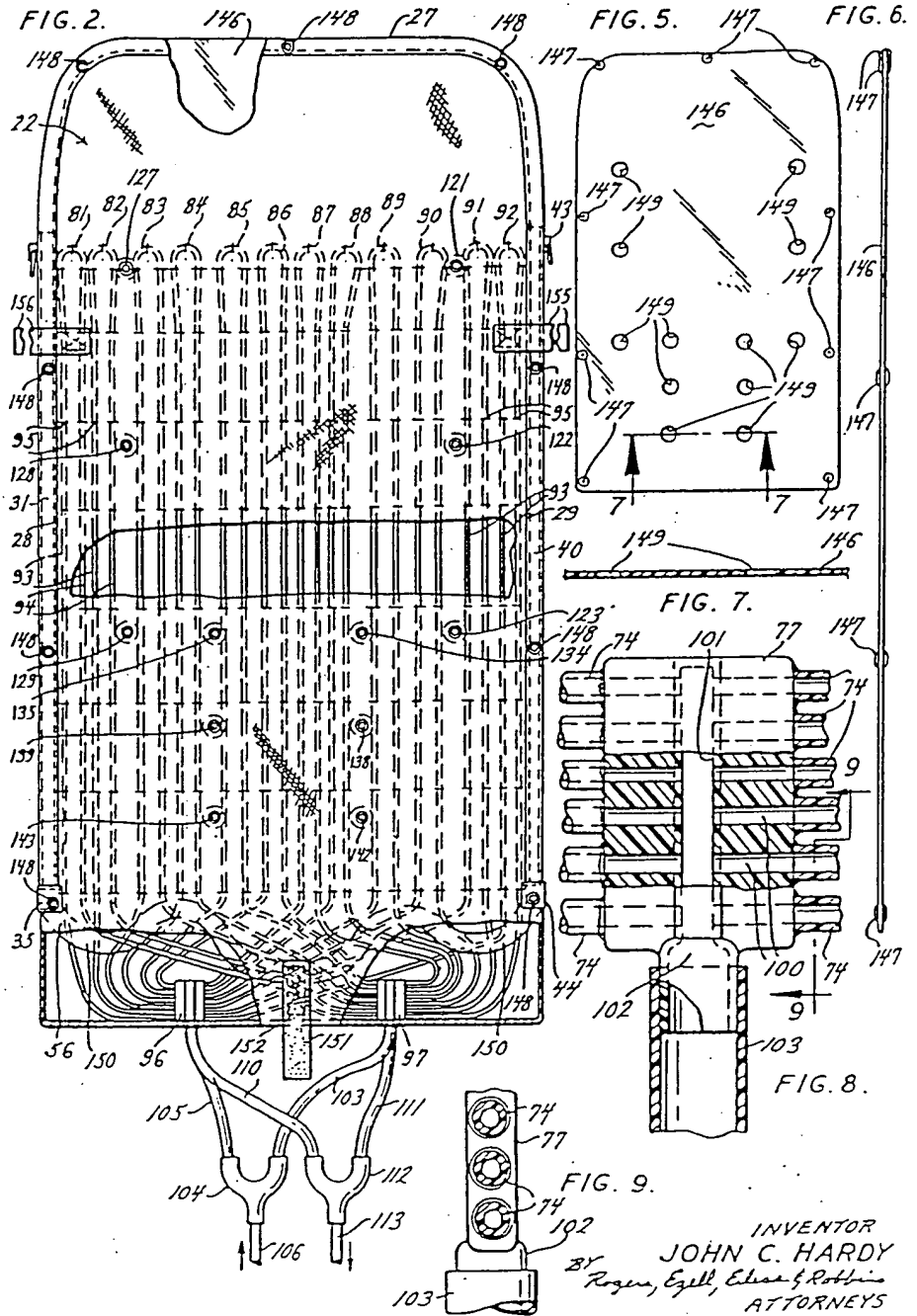
[57] ABSTRACT

An infant's hypothermia bunting having front and rear panels of two-way stretch fabric. Longitudinally extending tubes connected to the front and rear panels for conveying temperature-controlled fluid. Snap fasteners for adjusting the lateral size of the bunting and snap fasteners for adjusting the longitudinal size of the bunting to conform to different infant body sizes. Zippers at the center and sides of the bunting to provide body access for hospital purposes. A plastic liner releasably fastened to the rear panel for distributing the loads of tube projections. A pocket at the bottom of the bunting for containing manifolds collecting inlet ends of the tubes and outlet ends of the tubes for common connections to the inlet and outlet fittings of a hypothermia machine.

9 Claims, 10 Drawing Figures







1 HYPOTHERMIA BABY BUNTING

This application is a continuation-in-part of application Ser. No. 114,607 filed on Feb. 11, 1971.

BRIEF DESCRIPTION OF THE INVENTION:

This infant's hypothermia bunting controls an infant's body temperature for hospital purposes, such as surgical operations. Loss of body heat during preparation for surgery produces adverse physiological effects which can be critical, particularly for premature infants. It is important that the body temperature of the infant be controlled efficiently and uniformly over the entire body of the infant.

Most prior art systems circulate water through plastic tube blankets or pads which are stiff and do not conform to the body, resulting in inefficient heat transfer and local hot and cold spots. These prior art systems that incorporate plastic blankets or pads are heavy and therefore preclude covering the front of the infant's body leaving large exposed body surface areas and consequent loss of body heat. The prior art systems include fluid transport tubes sandwiched between two impermeable plastic plys, limiting sterilization and laundering. They are very uncomfortable, particularly to those areas of the infant's body that rest on body supporting surfaces. The impermeable construction limits breathing and evaporation of body moisture, adding to discomfort.

This infant's hypothermia garment comprises front and rear panels of stretch fabric. The panels are rectangular in shape and are joined at their sides and bottom edges. The upper edges are separable to provide an opening for receiving an infant's body into the envelope between the front and rear panels.

The bunting encloses the body of the infant from the neck down. Several fluid conveying tubes are attached to the inner surfaces of the panels by stitching or by an attachment method set forth in a co-pending application of the present inventor filed in close proximity to the filing date of the present application and identified as Rogers, Ezell, Eilers and Robbins Docket 16,484 entitled Method of Joining Tubes to Fabrics. The tubes extend longitudinally along the panels to permit and not interfere with lateral or circumferential expansion of the bunting to conform to the contour of the infant's body. Each tube consists of a supply pass and a return pass. The supply passes lead from inlet manifolds, and the return passes return to outlet manifolds. The manifolds are located in a pocket at the bottom of the bunting and are connected by tubes to a hyperthermia machine that circulates temperature-controlled fluid through the tubes. The supply passes and return passes are alternated to effect substantially uniform temperature distribution over the entire inner surfaces of the bunting.

Two longitudinal lines of snap fasteners are spaced inwardly of the side edges of the front and rear panels for adjustment of the width of the inner envelope of the bunting. Three lateral lines of snap fasteners are spaced upwardly from the lower edges of the front and rear panels to adjust the depth of the inner envelope. These snap fasteners thus vary the effective volume of the bunting so that it can be made to conform to different sizes and shapes of infant's bodies, with the stretch fabric material of the bunting providing further conformity to the contour of the infant's body.

A plastic liner has snap fasteners around its edges for releasable fastening to the inner surface of the rear panel to distribute the load and pressure created by the fluid conveying tubes. The panel is removable for sterilization of the panel and for sterilization and laundering of the bunting.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front elevation view of the infant's hypothermia bunting with parts broken away;
FIG. 2 is a rear elevation view of the infant's hypothermia bunting with parts broken away;
FIG. 3 is an enlarged fragmentary right side elevation view taken along the line 3—3 of FIG. 1;
FIG. 4 is an enlarged fragmentary right side elevation view taken along the line 4—4 of FIG. 1;
FIG. 5 is a front elevation view of the plastic liner on a reduced scale;
FIG. 6 is a right side elevation view of the plastic liner of FIG. 5 on the scale of FIGS. 1 and 2;
FIG. 7 is an enlarged fragmentary view in section taken along the line 7—7 of FIG. 5;
FIG. 8 is a front elevation view of an enlarged scale of a manifold with parts shown in section;
FIG. 9 is a fragmentary view in section taken along the line 9—9 of FIG. 8;
FIG. 10 is a schematic view of the connections of the manifold to a hyperthermia machine.

DETAILED DESCRIPTION OF THE INVENTION

This bunting 20 has a front panel 21 that is about 18 inches wide and 24 inches long and a rear panel 22 that is the same width as the front panel and is about 30 inches long. The foregoing lengths are exclusive of a bag at the lower end of the bunting to be described hereinafter. The front panel 21 has an upper edge 23 with a downwardly curved center 24 positioned where the neck of an infant within the bunting would be located, and has side edges 25 and 26. The rear panel 22 has an upper edge 27 that is about 6 inches above the upper edge 23 of the front panel and has side edges 28 and 29. The side edges 26 and 28 of the front and rear panels respectively are sewed to the front and rear cloth bindings 30 and 31 of a zipper 32. The zipper 32 has a separator start element 33 at its upper end and a slider 34 that can fully open the zipper 32 with the upper ends separated down to a cloth stop element 35 at the lower end of the zipper that is sewn to the front and rear panels 21 and 22.

The other side edges 25 and 29 of the front and rear panels respectively are similarly sewn to the front and the rear cloth bindings 39 and 40 of a zipper 41. The zipper 41 has a separator start element 42 at its upper end and a slider 43 that can open the zipper 41 with the separator element 42 separated and the zipper 41 separated all the way down to a cloth stop element 44 that is sewn to the front and rear panels 21 and 22 at the lower end of the zipper 41.

A zipper 48 extends longitudinally along the center of the front panel 21. The side cloth bindings 49 and 50 of the zipper 48 are sewn to the front panel 21. The zipper 48 has a separator start element 51 at its upper end. A slider 52 can open the zipper 48 with the separator element 51 separated and the zipper 48 separated all the way down to a cloth stop element 53 sewn to the front panel 21 at the lower end of the zipper 48.

The front and rear panels 21 and 22 continue below the cloth zipper stop elements 35, 44 and 53 and are sewn together at their side and bottom edges to form a bag 56. A lateral zipper 57 having a slider 58 provides access to the interior of the bag 56.

There are 12 tubes 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72 and 73 extending longitudinally of and fastened to the inner surface of the front panel 21, six of the tubes 62 through 67 being fastened to the front panel between the zippers 41 and 48 and the other six tubes 68 through 73 being fastened to the front panel between the zippers 48 and 32. Each tube 62 through 73 has a supply pass 74 and a return pass 75. The tubes 62 through 73 may be attached to the panel 21 by stitches 76 spaced at about 3-inch intervals or they may be attached by the method set forth in a co-pending application of the present inventor filed at about the same time as the present application and identified by Rogers, Ezell, Eilers and Robbins Docket 16484, entitled Method of Joining Tubes to Fabrics. The tubes 62 through 73 are arranged such that supply passes 74 alternate with return passes 75 and are substantially evenly spaced to distribute temperature-controlled fluid uniformly over the entire surface area of the bunting.

The lower ends of the supply passes 74 of the tubes 62 through 73 extend downwardly into the bag 56 and are connected to a supply or inlet manifold 77. The lower ends of the return passes 75 of the tubes 62 through 73 extend downwardly into the bag 56 and are connected to a return or outlet manifold 78.

Twelve tubes 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, and 92 are fastened to the inner surface of the rear panel 22. Each tube 81 through 92 has a supply pass 93 and a return pass 94. The tubes 81 through 92 are substantially evenly spaced across the width of the panel 22 with supply and return passes 93 and 94 alternating with one another and substantially evenly spaced. The tubes are connected to the panel 22 by spaced stitches 95 or by the method of the aforesaid co-pending application. All the ends of the supply passes 93 extend downwardly into the bag 56 and are connected to a supply or inlet manifold 96. The lower ends of the return passes 94 extend downwardly into the bag 56 and are connected to a return or outlet manifold 97. The tubes 62 - 73 and 81 - 92 are small and flexible being about one-eighth inch to five-thirty seconds inch in outside diameter.

FIG. 8 illustrates a typical manifold 77, the other manifolds 78, 96, and 97 being identical thereto. The tubes 74 are connected to the manifold 77, each communicating with a passage 100. Each passage 100 communicates with a central passage 101 provided by a central tube 102 to which a tube 103 is connected. These manifolds may be made by the process set forth in the present applicant's co-pending application filed at about the same time as the present application and being identified as Rogers, Ezell, Eilers & Robbins Docket 16485 entitled Method Of Joining Tubes To A Manifold.

In the case of the supply manifold 77, the tube 103 leads from a Y fitting 104. The other supply manifold 96 similarly has a tube 105 leading from the Y fitting 104. A tube 106 leads to the Y fitting 104 from an outlet connector 107 of a hyperthermia machine 108 of a conventional kind that circulates temperature-con-

trolled fluid, such as water. The tube outlet manifolds 78 and 97 have tubes 110 and 111 respectively leading to a Y junction 112. A tube 113 from the Y junction 112 leads to an inlet connector 114 to the hyperthermia machine 108.

This infant's hypothermia bunting has sizing adjustments that permit it to accommodate infants up to the age of about six months. Three snap fasteners 118, 119 and 120 are arranged in a longitudinal row and are joined to the front panel 21. The snap fasteners 118, 119, and 120 are spaced inwardly about three inches from the left side edge of the front panel 21. Three snap fasteners 121, 122, and 123 that are complementary to the snap fasteners 118, 119, and 120 are joined to the rear panel 22. The snap fasteners 121, 122, and 123 are in a longitudinal row and are located directly opposite the snap fasteners 118, 119, and 120.

A similar row of three snap fasteners 124, 125, and 126 is spaced about three inches longitudinally inwardly from the right front edge of the bunting. The snap fasteners 124, 125, and 126 are joined to the front panel and are located directly opposite three snap fasteners 127, 128 and 129 that are joined to the rear panel 22.

Two snap fasteners 132 and 133 are laterally aligned with the snap fasteners 120 and 126 and are joined to the front panel 21. The line of snap fasteners 120, 132 133 and 126 is spaced above the lower edge of the bunting 20 by about eleven inches, the lower edge being defined as an imaginary line through the fabric zipper stops 44, 53, and 35 above the bag 56. Two snap fasteners 134 and 135 are joined to the rear panel 22 in positions directly opposite the snap fasteners 132 and 133 and in line with the snap fasteners 129 and 123. The snap fasteners 134 and 135 are complementary to the snap fasteners 132 and 133.

Two laterally aligned snap fasteners 136 and 137 are joined to the front panel 21 approximately 4 inches below the snap fasteners 132 and 133. Two snap fasteners 138 and 139 that are joined to the rear panel 22 are opposite to and complementary to the snap fasteners 136 and 137. Another two snap fasteners 140 and 141 are laterally aligned and spaced approximately four inches below the snap fasteners 136 and 137 and are joined to the front panel 21. Two complementary snap fasteners 142 and 143 are joined to the rear panel 22 and are positioned opposite the snap fasteners 140 and 141.

The lines of longitudinal snap fasteners 118 and 119 and 120 and 121, 122, and 123 and the lines of longitudinal snap fasteners 124, 125, and 126 and 127, 128 and 129 can be snapped together to reduce the circumferential size of the bunting 20, or just one longitudinal line of snap fasteners may be snapped together, thus providing circumferential adjustment to an infant's body size. The lateral line of snap fasteners 120, 132, 133, and 126 may be snapped to the snap fasteners 123, 134, 135, and 129 for depth adjustment. Alternatively, the snap fasteners 136, 137, 138, and 139 may be snapped together or the snap fasteners 140, 141, 142, and 143 may be snapped together to provide variations in depth adjustment for infant body lengths. Following such coarse adjustment of the inner envelope, the stretch fabric of the panels 21 and 22 causes the bunting to conform to the body of the infant.

A plastic liner 146 is shaped to overlie the inner surface of the rear panel 22, forward of and overlying the tubes 81 - 92. The plastic liner 146 has spaced snap fasteners 147 adjacent to its upper and side edges. The rear panel 22 has forwardly projecting spaced snap fasteners 148 adjacent its upper and side edges complementary to the snap fasteners 147. The liner 146 also has holes 149 through it located to permit the various size adjustment snap fasteners 118 through 129 and 132 through 143 to be snapped together. All adjustment snap fasteners are reinforced by the plastic discs to prevent the snaps from pulling from its mounting substrate.

In use, an infant's body from the neck down is located within the envelope between the front and rear panels 21 and 22. Depending upon the size of the infant's body, different ones of the size adjustment snap fasteners are snapped together or, for a relatively large infant, all the size adjustment snap fasteners are left un-snapped. The front zipper 48 and two side zippers 32 and 41 can be unzipped for easier entry of the infant into the bunting. Also, these zippers provide flexibility of access to the infant's body for hospital and surgical purposes.

With the infant in the bunting, the stretch fabric holds the bunting in conformity with the infant's body. Temperature controlled fluid is circulated through the one-eighth to five thirty-seconds inch outside diameter tubes 62 through 73 and 81 through 92 so that the infant's body heat can be maintained at a desired level even in relatively cool operating atmospheres. The liner 146 eliminates pressure points from the tubes 81 through 92. For laundering and sterilization of the bunting, the lining 146 can be removed. This permits sterilization of the liner 146 also.

Thus, this infant's hypothermia bunting provides efficient heat transfer to the infant's body. The two directional stretch fabric of the front and rear panels 21 and 22 conforms the tubes to the infant's body. The alternating of supply and return passes of the tubes provides substantially uniform temperature distribution over the entire surfaces of the front and rear panels 21 and 22. At the same time, comfort is provided by the porosity of the fabric of the front and rear panels 21 and 22.

The bunting is light in weight and the fabric is soft and flexible so that is not uncomfortable when resting on the infant's body. The rear liner 146 distributes the loads that otherwise would be caused by the protruding profiles of the tubes 81 through 92. This liner is made of high thermal conductivity plastic for increased heat transfer.

With the adjustment snap fasteners, the bunting can be sized to fit all infants up to the age of about 6 months. The locations of the size adjustment snap fasteners tapers the inside envelope to conform to the natural taper of the torso and legs of the infant.

Zipper bindings 30, 31, 39 and 40 and Zipper stop elements 35 and 44 made from electrostatically conductive cloth and communicate electrostatically with another conductive cloth strip 150 located inside the pouch 56. The conductive cloth strip 150 is attached directly to zipper stop elements 35 and 44, and also to a conductive velcro pile strip 151 (pile facing down) located along the pouch centerline to electrostatically ground the bunting to the operating table. Strip 151 is

secured to the outer rear surface of pouch 56 along the centerline of the bunting with stitching 152.

Velcro pile tabs 155 and 156 (approximately 2 inches by 10 inches) are attached to the outside rear panel 22 surface by stitches (approximately 2 inches of stitching and 8 inches free length). Velcro hook tabs 153 and 154 are located along the zipper bindings 50 and 49 respectively in the same horizontal line as tabs 155 and 156. The tabs are so arranged that when the right-hand side of front panel 21, as viewed in FIG. 1, is opened and folded or rolled back to permit surgery on the left side of an infant, the tabs 156 and 154 are pressed together to hold that right-hand side firmly against the infant's torso. Conversely, when the left-hand side of front panel 21 is opened and folded or rolled back to permit surgery on the right side of an infant, the tabs 155 and 153 are pressed together to hold that left-hand side firmly against the infant's torso. When not required, the tabs 155 and 156 are folded under the rear panel 22 of the bunting.

Various changes and modifications may be made within this invention as will be readily apparent to those skilled in the art. Such changes and modifications are within the scope and teaching of this invention as defined by the claims appended hereto.

What Is Claimed is:

1. An infant bunting for enclosing the body of an infant and for controlling the body temperature of said infant comprising a flexible enclosure sized to receive said body of said infant, said enclosure having a front portion disposable in register with the front of said body of said infant and having a rear portion disposable in register with the rear of said body of said infant, tubing which is connected to the surface of said front portion of said enclosure in a pattern distributing said tubing over substantially the entire surface of said front portion of said enclosure that contacts said front of said infant's body and which confines and guides heat-exchanging fluid for movement in heat-exchanging relation with respect to said front of said infant's body, further tubing connected to the surface of said rear portion of said enclosure in a pattern distributing said further tubing over substantially the entire surface of said rear portion of said enclosure that contacts said rear of said infant's body and which confines and guides heat-exchanging fluid for movement in heat-exchanging relation with respect to said rear of said infant's body, means to control the temperature of said heat-exchanging fluid moving through the first said tubing and also through said further tubing, releasable fastener means on said front portion of said enclosure which are spaced inwardly from edges of said front portion of said enclosure, and complementary releasable fastener means on said rear portion of said enclosure which are spaced inwardly from edges of said rear portion of said enclosure, the first said releasable fastener means being in register with and being selectively securable to and releasable from said complementary releasable fastener means, the first said releasable fastener means and said complementary releasable fastener means being releasable from each other to permit a large amount of the area of said front portion of said enclosure to be moved far enough away from a corresponding amount of the area of said rear portion of said enclosure to enable said bunting to accom-

moderate but confine the body of a large infant, the first said releasable fastener means and said complementary releasable fastener means being securable together to join said front portion of said enclosure to said rear portion of said enclosure at points which are spaced inwardly of said edges of said front portion and of said rear portion of said enclosure, and thereby reduce the amount of area of said front portion of said enclosure which can be moved far enough away from a corresponding amount of the area of said rear portion of said enclosure to accommodate but confine the body of a smaller infant, whereby selective securing or releasing of the first said releasable fastener means and of said complementary releasable fastener means readily and directly varies the effective size of said bunting for conformance of said bunting to the bodies of infants of varying sizes.

2. The infant bunting of claim 1 wherein said front portion of said enclosure is a front panel, wherein said rear portion of said enclosure is a rear panel, wherein the first said releasable fastener means are individual and discrete fasteners longitudinally aligned and spaced inwardly from the side edges of said front panel and are further individual and discrete fasteners laterally aligned and spaced upwardly from the lower edge of said front panel, wherein said complementary releasable fastener means are individual and discrete fasteners longitudinally aligned and spaced inwardly from the side edges of said rear panel and are further individual and discrete fasteners laterally aligned and spaced upwardly from the lower edge of said rear panel, whereby the first said releasable fastener means and said complementary releasable fastener means coact to permit said effective size of said bunting to be adjusted longitudinally as well as laterally.

3. The infant bunting of claim 1 wherein said front portion of said enclosure is made of stretch fabric that is stretchable in at least the lateral direction, wherein said rear portion of said enclosure is made of stretch fabric that is stretchable in at least the lateral direction, wherein the first said releasable fastener means and said complementary releasable fastener means coact to provide a coarse size adjustment in the lateral direction, and wherein the stretchable nature of said stretch fabric of said front portion and of said rear portion of said enclosure enable said front portion and said rear portion of said enclosure to provide a fine size adjustment in the lateral direction.

4. The infant bunting of claim 1 wherein the first said tubing is fluid conveying tubing, wherein said further tubing is fluid conveying tubing, wherein the first said tubing comprises a plurality of individual tubes each having a supply span and a return span, wherein the tube spans of the first said tubing are located with supply spans alternating with return spans for uniform temperature distribution over the surface of said front portion of said enclosure, wherein said further tubing comprises a further plurality of individual tubes each having a supply span and a return span, wherein the tube spans of said further tubing are located with supply spans alternating with return spans for uniform temperature distribution over the surface of said rear portion of said enclosure, wherein supply manifold means supply fluid to said supply spans of the first said and said further tubing, and wherein return manifold

means receive fluid from said return spans of the first said and said further tubing.

5. The infant bunting of claim 1 wherein said front portion of said enclosure is a front panel, wherein said rear portion of said enclosure is a rear panel, wherein the first said releasable fastener means are individual and discrete fasteners, wherein said complementary releasable fastener means are further individual and discrete fasteners, wherein a pressure-distribution liner is releasably fastened to said rear panel, wherein said pressure-distribution liner overlies said further tubing and can distribute evenly to said body of said infant the forces which said further tubing otherwise would distribute unevenly to said body of said infant, and wherein said pressure-distribution liner has openings therein in register with the first said and said further releasable fastener means to enable the first said and said further releasable fastener means to engage each other through said openings.

6. An infant bunting for controlling body temperature comprising front and rear panels joined at their side and bottom edges to form a pocket open at its upper end to receive the body of an infant, a plurality of small-diameter tubes fastened in a substantially uniformly spaced array to a surface of said front panel, a second plurality of small-diameter tubes fastened in a substantially uniformly spaced array to a surface of said rear panel, each tube of the first said plurality of small-diameter tubes having a supply span for receiving temperature-controlled fluid and a return span for returning said temperature-controlled fluid after said temperature-controlled fluid has been in heat-exchanging relation with said body of said infant, each tube of said second plurality of small-diameter tubes having a supply span for receiving temperature-controlled fluid and a return span for returning said temperature-controlled fluid after said temperature-controlled fluid has been in heat-exchanging relation with said body of said infant, distributor means to receive said temperature-controlled fluid from a source of temperature-controlled fluid and to supply said temperature-controlled fluid to said supply spans of said tubes of the first said plurality of small-diameter tubes and to supply said temperature-controlled fluid to said supply spans of said tubes of said second plurality of small-diameter tubes and thereby enable the first said plurality and said second plurality of small-diameter tubes to circulate temperature-controlled fluid in heat-exchanging relation with said body of said infant, further distributor means connected to said return spans of said tubes of the first said plurality of small-diameter tubes and to said return spans of said tubes of said second plurality of small-diameter tubes to receive said temperature-controlled fluid from said tubes of the first said plurality and said second plurality of small-diameter tubes after said temperature-controlled fluid has been in heat-exchanging relation with said body of said infant and to return said temperature-controlled fluid to said source of temperature-controlled fluid, releasable fastener means on said front panel that are distributed longitudinally and laterally of said front panel, complementary releasable fastener means on said rear panel that are distributed longitudinally and laterally on said rear panel, the first said releasable fastener means and said complementary releasable fastener means being

releasable to permit large amounts of the confronting areas of said front panel and of said rear panel to be moved apart to accommodate the body of a large infant, some of the longitudinally-distributed releasable fastener means of the first said releasable fastener means and some of the longitudinally-distributed releasable fastener means of said complementary releasable fastener means being securable together to reduce the amounts of said confronting areas of said front and said rear panels which can be moved apart to accommodate the body of an infant and thereby enable said bunting to accommodate and closely confine the body of an infant of smaller girth, some of the laterally-distributed releasable fastener means of the first said releasable fastener means and some of the laterally-distributed releasable fastener means of said complementary releasable fastener means being securable together to reduce the amounts of said confronting areas of said front and said rear panels which can be moved apart to accommodate the body of an infant and thereby enable said bunting to accommodate and closely confine the body of an infant of shorter height, whereby the first said releasable fastener means and said complementary releasable fastener means enable said bunting to accommodate and closely confine the bodies of infants of differing girths and differing heights.

7. The infant bunting of claim 1 wherein zippers selectively connect and free the edges of openings in said enclosure, wherein said zippers have electrostatically conductive zipper bindings, wherein said enclosure has electrostatically conductive cloth strips, and wherein said electrostatically conductive zipper bindings and said electrostatically conductive cloth strips are in communication electrostatically with a central conductive tab to permit grounding of the bunting to the operating table by placing said central conductive tab in engagement with said operating table.

8. The infant bunting of claim 1 wherein said front portion of said enclosure is subdivided into two sides, wherein each of said two sides is selectively movable to an open position wherein it is spaced away from the corresponding side of the front of the body of an infant disposed within said enclosure to permit medical procedures to be carried out on said corresponding side of said front of said body of said infant, wherein each of said two sides is selectively movable to a closed position wherein it is in intimate contact with the corresponding side of said front of said body of said infant, and wherein adjustable releasable circumferential fastener tabs span the opened side of said bunting during medical procedures thereby maintaining the closed side of the bunting in intimate contact with the corresponding side of said front of said body of said infant.

9. An infant bunting for enclosing the body of an infant and for controlling the body temperature of said infant comprising an enclosure which is made of stretch fabric that is stretchable in at least the lateral direction, said enclosure having a front panel disposable in register with the front of the body of an infant and having a rear panel disposable in register with the rear of said body of said infant, said front panel and said rear panel being sized to enable said enclosure to accommodate the body of a large infant with only limited stretching of said stretch fabric in said lateral direction, fluid-conveying tubing secured to said front panel of said en-

closure in a pattern distributing said fluid-conveying tubing over substantially the entire surface of said front panel of said enclosure that contacts said front of said infant's body to confine and guide heat-exchanging fluid for movement in heat-exchanging relation with respect to said front of said infant's body, further fluid-conveying tubing secured to said rear panel of said enclosure in a pattern distributing said further fluid-conveying tubing over substantially the entire surface of said rear panel of said enclosure that contacts said rear of said infant's body to confine and guide heat-exchanging fluid for movement in heat-exchanging relation with respect to said rear of said infant's body, the first said fluid-conveying tubing including a plurality of individual tubes that have supply spans and return spans, said plurality of individual tubes of the first said fluid-conveying tubing being disposed so the supply and return spans of the first said fluid-conveying tubing alternate to provide uniform temperature distribution over substantially the entire surface of said front panel of said enclosure that contacts said front of said infant's body, said further fluid-conveying tubing including a further plurality of individual tubes that have supply spans and return spans, said further plurality of individual tubes of said further fluid-conveying tubing being disposed so the supply and return spans of said further fluid-conveying tubing alternate to provide uniform temperature distribution over substantially the entire surface of said rear panel of said enclosure that contacts said rear of said infant's body, supply manifold means to supply heat-exchanging fluid to said supply spans of said plurality of individual tubes of the first said fluid-conveying tubing and to said supply spans of said further plurality of individual tubes of said further fluid-conveying tubing, return manifold means to receive heat-exchanging fluid from said return spans of said plurality of individual tubes of the first said fluid-conveying tubing and from said return spans of said further plurality of individual tubes of said further fluid-conveying tubing, a plurality of individual and discrete releasable fasteners secured to said front panel of said enclosure and spaced longitudinally and laterally of said front panel of said enclosure, said plurality of releasable fasteners being spaced inwardly from the side and bottom edges of said front panel of said enclosure, a plurality of complementary individual and discrete releasable fasteners secured to said rear panel of said enclosure and spaced longitudinally and laterally of said rear panel of said enclosure, said complementary plurality of releasable fasteners being spaced inwardly from the side and bottom edges of said rear panel of said enclosure, the releasable fasteners of the first said plurality of releasable fasteners being in register with and being selectively securable to and releasable from the releasable fasteners of said complementary plurality of releasable fasteners, the releasable fasteners of the first said plurality of releasable fasteners and the releasable fasteners of said complementary plurality of releasable fasteners being releasable from each other to permit a large amount of the area of said front panel of said enclosure to be moved far enough away from a corresponding amount of the area of said rear panel of said enclosure to enable said bunting to accommodate but confine the body of said large infant, some of the longitudinally-spaced releas-

ble fasteners of the first said plurality of releasable fasteners and some of the longitudinally-spaced releasable fasteners of said complementary plurality of releasable fasteners being securable together to reduce the amounts of said confronting areas of said front and said rear panels which can be moved apart to accommodate the body of an infant and thereby enable said bunting to accommodate and closely confine the body of an infant of smaller height, some of the laterally-spaced releasable fasteners of the first said plurality of releasable fasteners and some of the laterally-spaced releasable fasteners of said plurality of complementary releasable fasteners being securable together to reduce the amounts of said confronting areas of said front and said rear panels which can be moved apart to accommodate the body of an infant and thereby enable said bunting to accommodate and closely confine the body of an infant of shorter girth, whereby the releasable fasteners of the first said plurality of releasable fasteners and said releasable fasteners of said plurality of complementary releasable fasteners enable said bunting to accommodate and closely confine the bodies of infants of differing heights and differing girths, said some of the laterally-spaced releasable fasteners of the first said plurality of releasable

fasteners and said some of the laterally-spaced releasable fasteners of said plurality of complementary releasable fasteners coacting to provide a coarse size adjustment for said enclosure in the lateral direction, the stretchable nature of said stretch fabric of said front panel and of said rear panel of said enclosure enabling said front panel and said rear panel of said enclosure to provide a fine size adjustment for said enclosure in the lateral direction, and a pressure-distribution liner that is releasably fastened to said rear panel, said pressure-distribution liner overlying said tubes of said further fluid-conveying tubing to distribute evenly to said body of said infant the forces which said tubes of said further fluid-conveying tubing otherwise would distribute unevenly to said body of said infant, said pressure-distribution liner having openings therein in register with said releasable fasteners of the first said plurality of releasable fasteners and in register with said releasable fasteners of said complementary plurality of releasable fasteners to permit securement of said releasable fasteners of the first said plurality of releasable fasteners to said releasable fasteners of said complementary plurality of releasable fasteners through said openings.

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United States Patent [19]

Augustine et al.

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[54] AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE

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[58] Field of Search 128/367, 368, 379, 380, 128/400, 402; 4/535, 536, 537; 34/99, 233, 243 R; 219/212; 165/46; 62/259.3, 261; 2/171.3; 126/204

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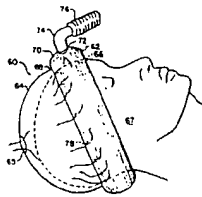
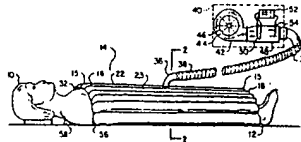
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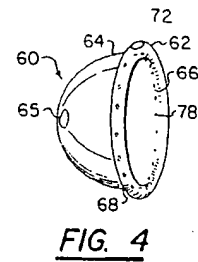
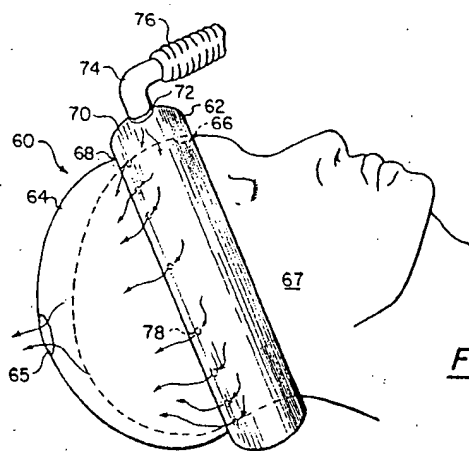
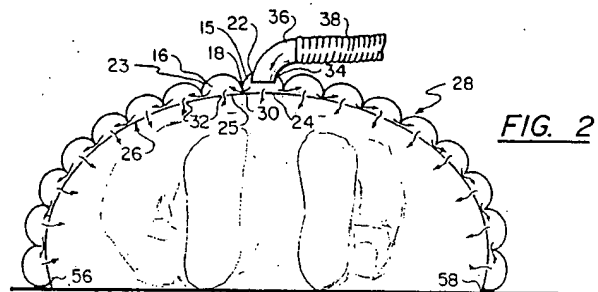
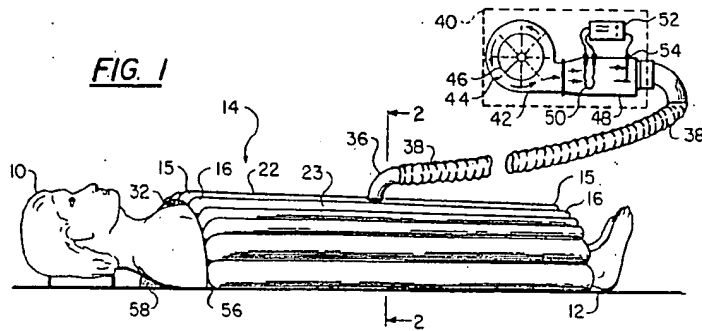
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[57] ABSTRACT

An airflow cover for controlling the body temperature of a patient covers a portion of the patient's body and provides a generalized thermal bathing of the covered portion through the delivery of a temperature controlled gas mixture to the covered portion. The cover is formed from a series of inflatable tubes which are joined together in a parallel array having an upper surface facing away from the patient's body and an oppositely directed lower surface which faces the covered portion of the patient's body. An entry port is provided through the upper surface and into one tube, transverse ports open between the tubes, and exit ports are formed in the lower surface. A thermally controlled gas mixture is introduced through the entry port, circulates in the tubes by means of the transverse ports and inflates the tubes, and exits through the exit ports in the direction of the covered body portion to provide the desired thermal bathing.

10 Claims, 4 Drawing Figures





AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE

BACKGROUND OF THE INVENTION

The cover of the invention relates generally to a cover used in a medical treatment environment to control the bodily temperature of a patient, and more specifically to such a cover which controls the temperature of a covered patient's body by bathing it with a temperature controlled gas mixture.

It is often the case that the bodily temperature of a patient who is about to undergo or who has undergone certain forms of medical treatment such as surgery must be regulated by lowering or elevating it to a predetermined average level. In existing apparatus, the generalized control of such a patient's temperature is provided by means of a pliable blanket through which a temperature controlled fluid is circulated. When the patient is covered with such a blanket, the temperature of the fluid is conducted to the patient to move the patient's temperature toward the desired level. However, most of the temperature exchange between the blanket and the patient takes place only at the points where the blanket contacts the patient's skin. This can result in localized thermal activity of a high rate where the blanket and the patient's skin are in contact, which results in the localized temperature of the contacted portion of the patient's body being either substantially above or below the desired average temperature. When the patient's body temperature is being elevated and the circulating fluid is heated, this can result in burning at the contacted areas. In addition, the heat transfer between the blanket and the portions of the patient's body which the blanket does not contact is radiative and therefore inefficient.

In other covers, the circulating heat transfer mechanism is temperature controlled air. In one such cover disclosed in U.S. Pat. No. 2,110,022, the air is circulated inside of a flexible bag which has a top insulating layer and a bottom heat conducting layer which contacts the patient. However, the structure of this blanket makes it unnecessarily heavy and rigid. The weight of the blanket can press its inner surface against the covered patient and block a number of the exit ports, thereby reducing the total body area over which the air circulated.

It is therefore desirable to provide a supple, lightweight cover for efficiently and effectively controlling the bodily temperature of a covered patient.

SUMMARY OF THE INVENTION

The cover of the present invention overcomes the limitations of existing covers which control the bodily temperature of the patient by providing a lightweight flexible, inflatable casing having an upper and a lower surface. The casing has an entry port penetrating its upper surface for permitting a thermally-controlled inflating medium to flow into and inflate the casing, and a plurality of exit ports formed in the lower surface for, when the casing is inflated, permitting the thermally-controlled medium to flow out of the casing's lower surface. The cover is placed over a patient and inflated by introduction of the medium through the entry port into a self-supporting structure which encloses the patient. The temperature-controlled inflating medium circulates through the inflated casing and exists through the exit ports on the lower surface which faces the

patient to provide the desired generalized thermal bathing of the patient's body.

Preferably, the casing is made from a plurality of elongated inflatable tubes, each of which is formed from a lightweight flexible material such as plastic. The tubes are joined together longitudinally to form a substantially parallel array, the opposing major surfaces of which form the upper and lower surfaces of the cover. An entry port is provided in the upper surface; transverse ports are provided between adjoining tubes; and a plurality of exit ports are provided in the lower surface of the array. The tubular structure of the cover and the material from which the tubes are formed enable the casing to inflate and to form a self-supporting structure when the cover is laid atop the patient. The tubular construction causes the cover to naturally wrap around the patient and provide a semi-enclosed, generally tubular structure which covers the patient. The inflating medium is preferably a gas mixture which is provided under pressure from a unit which exchanges energy with the mixture. The light weight of the casing permits it to be partially supported by the air escaping through the exit ports which prevents the cover from blocking the ports by contacting the covered body portion.

The unit is connected to the input port by means of a delivery hose and has a blower assembly for forcing the mixture into the cover. In the preferred embodiment, the gas mixture constitutes ambient air which is heated to a desired temperature level and blown through the delivery hose to the cover and delivered therefrom through the exit ports to thermally bathe the patient.

It is therefore the principal object of the present invention to provide an airflow cover which controls the body temperature of a patient by delivering a diffused flow of a thermally-controlled gas mixture which results in a generalized thermal bathing of the patient.

It is a further object of the present invention to provide such a cover which is inflated by the temperature-controlled mixture into a self-supporting structure which substantially encloses the patient and thereby increases the efficiency of the generalized thermal bathing.

Other objects and advantages of the present invention will become apparent when the description of the preferred embodiment is read in conjunction with the following drawing figures:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the airflow cover of the invention in a representative operational environment.

FIG. 2 is a partial sectional view of the cover of the invention with the cross section of the cover taken along lines 2-2 of FIG. 1.

FIG. 3 is an illustration of a representative application environment for a second embodiment of the airflow cover of the invention where the cover is used to thermally bathe a portion of a patient's body.

FIG. 4 is a perspective view of the embodiment illustrated in FIG. 3.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to FIG. 1, the reader will understand the operational application of the preferred embodiment of the air-flow cover of the invention. In FIG. 1 a patient 10 is shown reclining on a surface which may comprise the upper surface of a gurney or a bed. Sur-

rounding the patient is the cover of the invention, illustrated generally by 14, which is shown placed over the patient and inflated into a substantially semi-tubular structure which encloses the major portion of the patient's midbody. In the illustrated operational application, the cover 14 is delivering a diffused stream of heated air by means disclosed in greater detail hereinbelow to the enclosed portion of the patient's body. Such an application would be useful, for example, where the patient's temperature has dropped below a medically safe average to a point where a peril of hypothermia is presented. In such a circumstance, it is desired to quickly and efficiently raise the patient's temperature in order to restore the temperature to as near normal as is possible.

The means by which the cover 14 accomplishes the desired purpose can be understood with reference to FIGS. 1 and 2. The cover 14 is made up of a plurality of parallel elongate plastic tubes, two of which are indicated by 15 and 16, interconnected to form an inflatable casing. It is to be understood that the description of the tube 16 precisely describes the remaining tubes which form the cover. As illustrated, the tubes 15 and 16 are joined together by a intermittent longitudinal seam 18. Each tube is formed from a flexible inflatable material, such as plastic. The use of plastic to form the tubes 15 and 16 permits the seal 18 to consist of either a heat seal or a cured epoxy seal which is sufficient to join the tubes as indicated. The tubes 15 and 16 have half-rounded cross-sectional shapes with rounded upper portions 22 and 23, respectively, and flattened lower portions 24 and 25, respectively. The lower flattened portions of all of the joined tubes together form a lower surface 26 and the rounded upper portions, a generally longitudinally quilted upper surface 28.

One or more transverse openings or ports 30 are provided through the seam 18 and through all of the seams to permit an inflating medium such as air to circulate between the tubes. A plurality of exit ports 32 are provided in the lower flattened portions of all of the tubes which permit the circulating medium to flow out of the tubes and through the lower cover surface 26. Although the ports 30 and 32 are shown aligned in FIG. 2, it should be evident that they may be alternately staggered into the plane of the cross section so that the illustration would then show alternate tubes with ports, the ports of the non-ported tubes being out of the plane of the section. A single input port 34 in the keystone tube 15 accepts the end nozzle 36 of a delivery hose 38, which is connected to a heater/blower assembly 40. The assembly includes a blower housing 42, a fan 44, and a motor 46 which is coupled to rotate the fan 44. The housing 42 is connected to and communicates with a heating manifold 48 in which is disposed a heating element 50 connected to a standard temperature controller 52. A thermistor probe 54 is also disposed in the manifold 48 between the heating element 50 and the end of the delivery hose 38.

In operation, the heater/blower assembly 40 causes air heated to a predetermined temperature to be blown through the delivery hose 38 and the nozzle 36 into the keystone tube 15 of the cover 14. The temperature-controlled air circulates from the keystone tube 15 through the transverse ports 30 into all of the other tubes which form the cover 14. The heater/blower 40 is operated to provide an input flow of heated air which has sufficient pressure to fully inflate all of the tubes of the cover 14 without causing any of them to burst. As the heated air

flows into the tubes and inflates them, the inflation pressure causes the heated air to be forced out of the exit ports 32. The air which is blown from the exit ports 32 provides the generalized thermal bathing of the patient 10. The arrows in FIG. 2 indicate the direction of circulation of the air from the delivery hose 38 through the cover 14 to the patient 10. When the cover 14 is placed over the patient 10 and inflated, the pressure of one tube against another is collected at the edges 56 and 58 of the cover which causes the edges to curl down around the patient toward the surface 12. However, the inflation of the tubes provides the cover 14 with a self-supporting structure having a generally rounded or elliptical cross-sectional shape which contacts the patient 10 only at the tubes which are immediately adjacent the keystone tube 15. The lightweight material from which the tubes are formed permits the air pressure which is exerted through the exit ports 32 of those tubes which are in contact with the patient to raise those tubes slightly so that circulation is provided through those exit ports. This is in contrast with the heavy structures of the existing airflow covers whose weight and structure block the ports which contact the patient. The cross-sectional structure illustrated in FIG. 2 enables the cover 14 to diffuse the temperature-controlled air which is delivered through the hose 38 into a generalized airflow which bathes as much of the patient's body as is covered by the cover 14. This convective operation increases the effectiveness and efficiency of the thermal exchange between the patient and temperature-controlled air without causing the localized thermal exchange of the existing circulating water blankets.

An alternate embodiment of the airflow cover of the invention is illustrated in FIGS. 3 and 4 wherein a scalp air-flow cover 60 includes an inflatable annular tube 62 to which is joined a generally rounded cap or enclosure 64 having an exit port 65. The annular tube has an inner surface 66 forming an opening which is placed over a portion of the head of a patient 67. Both the tube 62 and the cap enclosure 64 are constructed from a lightweight, flexible material, such as thermally-formed sheet plastic. The two pieces are joined by a continuous air-tight seam 68. The annular tube 62 has an outer surface 70 through which a port 72 is provided which accepts the nozzle 74 of a delivery hose 76. The delivery hose 76 is connected to a heater/blower assembly (not shown) which is identical in all respects to the heater/blower assembly 40 of FIG. 1. On the inner surface 66 of the annular tubes 62 and adjacent the seam 68, a plurality of exit ports 78 are provided. The exit ports are formed in the tube to be on the interior of the heating cap 60 when it is placed on the head of the patient 61. In operation, when pressurized or flowing air is introduced through the delivery hose 76, the annular tube 62 is inflated, with the inflating air being forced under pressure out of the exit ports 78. When the tube 62 is inflated it forms a contact barrier between itself and the head of the patient 67 so that air which flows out of the exit port 78 is forced into the end portion 64, circulates therein and exits through the end portion exit port 65. Thus, the annular tube 62 diffuses the flow of air delivered by the hose 76, with the tube and the end portion 64 providing a generalized thermal bathing of the scalp and head of the patient 67. It should be evident that when the tube 62 inflates, it slightly raises the head of the patient 67, thereby providing an air passage between the lower portion of the patient's head and the end portion 64. It should be further evident that this

maximizes the area of the patient's scalp which is thermally bathed.

Although the embodiments of the invention are described as operating in conjunction with heated air, it should be evident to those skilled in the art that a source of pressurized cooled air will provide a generalized cooling bath using either of the cover embodiments described hereinabove to control the body temperature of the patient under conditions of hyperthermia. Moreover, it should be evident that, while the inflating and bathing mixture was described as heated air, any medium which is sufficiently vaporized can be used to inflate either embodiment of the cover and to provide the generalized thermal bathing. Moreover, it is possible to suspend an aerosol in the inflating and circulating medium, which can include a disinfectant for treatment of burned areas of the patient's body.

Obviously, many modifications and variations of the described embodiments are possible in light of the above teachings, and it is therefore understood that the invention may be practiced otherwise than as specifically described.

We claim:

1. A cover for delivering a diffuse medium flow to a human body, comprising:

an inflatable cover housing including a plurality of inflatable hollow tubes, each tube having a rounded upper portion and a flattened lower portion, joined in a substantially parallel array to form a substantially smooth lower cover surface including said lower tube portions for facing a body to be covered and a quilted upper cover surface including said upper tube portions for facing away from said body;

an entry port in said upper surface for admitting an inflating medium into said housing;

transverse openings connecting the interior of each tube with the interior of at least one other adjacent tube in said array for conducting an inflating medium into all of said tubes to inflate said housing; and

exit ports formed in the flattened portion of each of said tubes for, when said housing is inflated, permitting said medium to flow out of said housing through said smooth lower surface.

2. The covering of claim 1 further including a source of a thermally controlled, inflating medium connected to said entry port means.

3. The covering of claim 2 wherein said medium comprises a gas mixture.

4. The covering of claim 3 wherein said gas mixture comprises air.

5. The covering of claim 1 wherein, when said housing is inflated and placed over a body, said housing assumes a tubular, self-supporting structure for substantially enclosing said body.

6. The covering of claim 1 wherein each said exit opening is substantially smaller than said entry opening.

7. The covering of claim 6 further including a source of a pressurized, thermally controlled gas mixture connected to said entry port means, wherein said thermally controlled gas mixture enters said array through said entry port, inflates said housing, and flows out from said inflated housing through said exit ports.

8. A cap for controlling the temperature of the head of a reclining person; comprising:

an inflatable annular tube forming a central opening for encirclingly fitting to the head of a person reclining on a support surface and for being inflated to lift said head from said surface;

a sheet of material attached to one side of said annular tube over said central opening to form a recess for receiving substantially the top of a head when said head extends into said recess through said central opening;

an outer surface on said tube;

an entry port on said tube outer surface for admitting a temperature-controlled, inflating medium into said tube;

an inner surface in said tube's central opening;

exit ports in said inner surface for, when said tube is inflated with an inflating medium, conducting said inflating medium from said tube into said recess; and

an exit port, substantially smaller than said central opening, in said material sheet for venting an inflating medium from said recess to an external environment.

9. The cap of claim 8 further including a source of thermally controlled, inflating medium connected to said entry port.

10. The cap of claim 9 wherein said medium comprises a gas mixture.

* * * *

United States Patent [19]

Greene, Jr.

[11] Patent Number: 4,660,388

[45] Date of Patent: Apr. 28, 1987

[54] COOLING COVER

[76] Inventor: George J. Greene, Jr., 616 N. Eldridge St., Houston, Tex. 77079

[21] Appl. No.: 780,280

[22] Filed: Sep. 26, 1985

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Primary Examiner—William E. Wayner
Attorney, Agent, or Firm—Vinson & Elkins

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. '613,913, May 24, 1984, abandoned.

[51] Int. Cl. A47K 13/00

[52] U.S. Cl. 62/261; 5/485; 98/1; 165/46

[58] Field of Search 62/261, 259.3; 5/485, 5/461; 165/46; 98/89, 1 R; 128/400, 402

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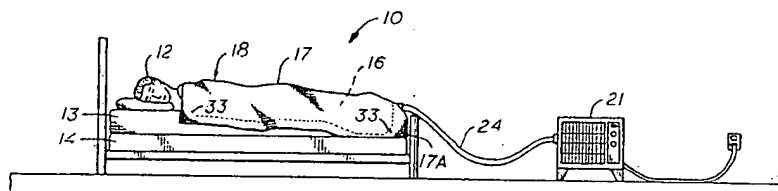
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2,093,834 9/1937 Gaugler 128/402 X

[57] ABSTRACT

A cooling cover (10) has an air inflatable pad (16) which may be positioned within a pocket (20) of a coverlet (18). The pad (16) formed of air impermeable material has plenum chambers (28) at opposite ends thereof, and a plurality of individual longitudinally extending passages (26) extend between the plenum chambers (28). Openings or air orifices (34) of a non-uniform pattern in the lower rounded surfaces of the inflatable pad (16) direct cooling air in a plurality of small air jets onto the body of a user of the cooling cover (10). A source of cool air (21) is connected to the inlet (30) for a plenum chamber (28) to deliver cool air to the pad (16).

5 Claims, 9 Drawing Figures



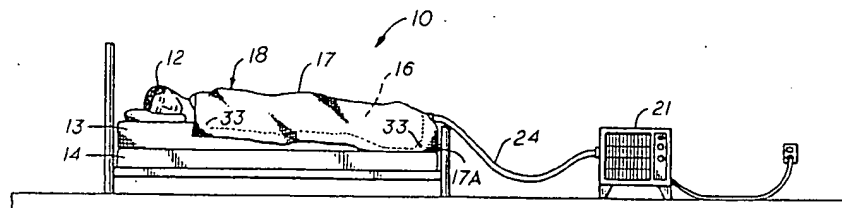


FIG. 1

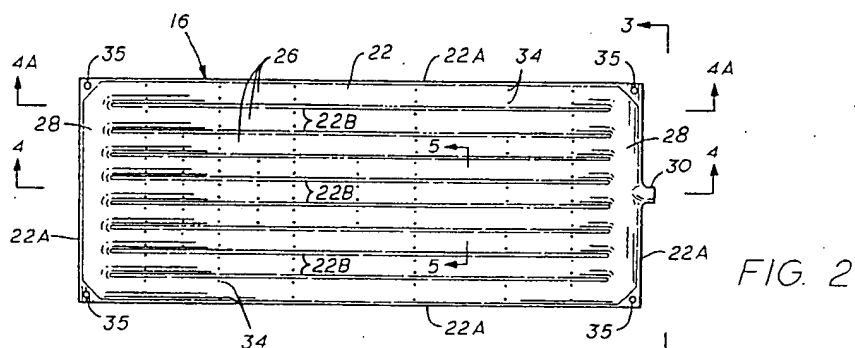


FIG. 2

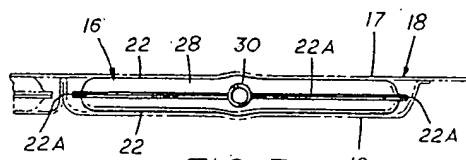


FIG. 3

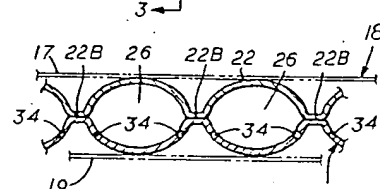


FIG. 5

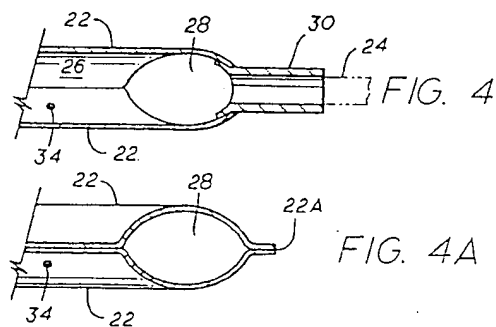
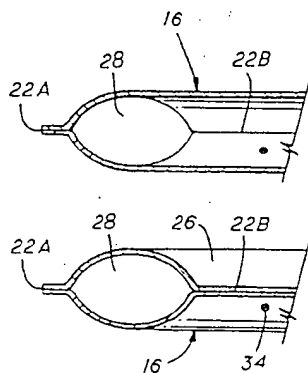


FIG. 4A

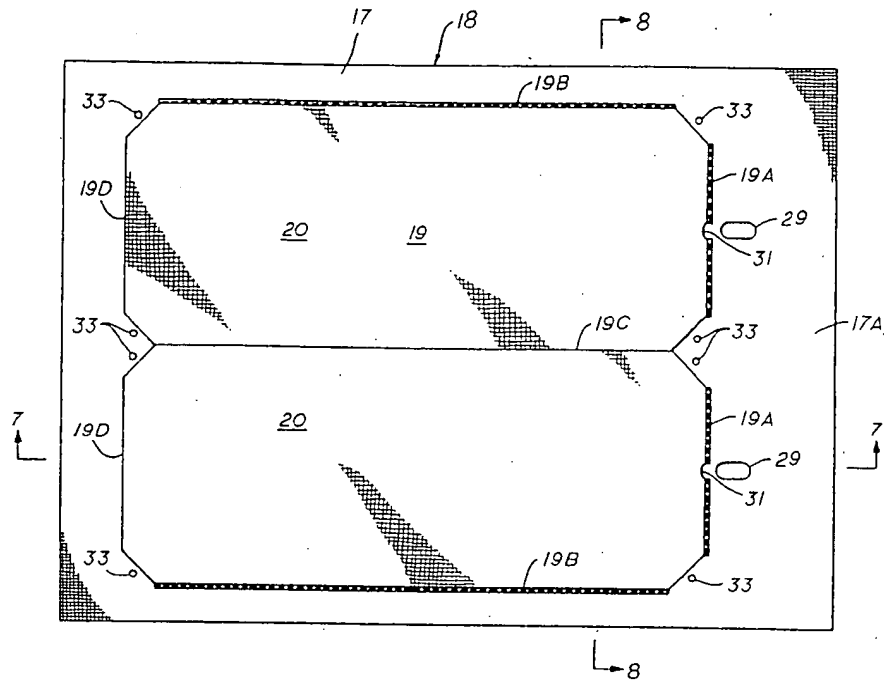


FIG. 6

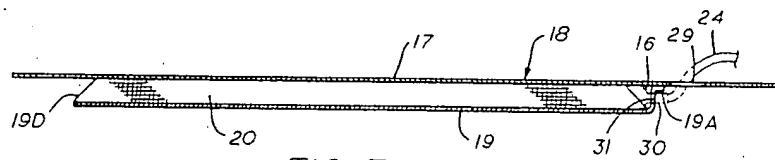


FIG. 7

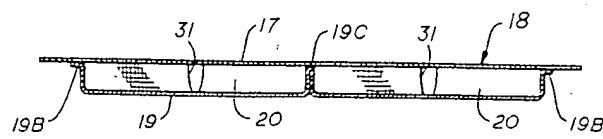


FIG. 8

COOLING COVER

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of application Ser. No. 613,913 filed May 24, 1984.

BACKGROUND

Individual cooling suits and blankets have been attempted to provide cooling of people. Much of the work on this type of equipment has been done in the design of suits to be worn in space. In these prior art devices, cooling is accomplished by circulating a cooling liquid through cooling coils in the suit and supplying cooling air to a helmet to assure the supply of a cool air for breathing and cooling of the individual's face. A typical example of this type of suit is disclosed in U.S. Pat. No. 4,095,593. A suit to be worn during operations in a hospital is shown in U.S. Pat. No. 3,738,367 and includes tubes through which cooling liquid from a hyperthermia machine is circulated.

Another type of suit is shown in U.S. Pat. No. 3,174,300 which recirculates air by a blower carried in the suit through a carbon dioxide absorber and a coolant tank. The garment shown in U.S. Pat. No. 3,479,838 utilizes a reduced pressure to cause water to boil in order to provide body cooling. A heat treating garment is shown in U.S. Pat. No. 3,610,251 which flows hot air into a baglike garment having apertures in the wrist or shoulders to allow escape of the hot air.

The R. S. Gaugler U.S. Pat. No. 2,093,834 discloses a refrigerating apparatus which can be used as a bed cover or as a garment. The cooling air or treating medium is supplied to an enclosure formed of sheeting and diffuses through the sheeting to cool the body of the individual under the apparatus.

None of these prior structures provide a simple structure which is suitable to cool an individual over a substantial portion of his body while he is asleep.

SUMMARY

The present invention provides a cooling cover to be used to cool an individual while sleeping or resting and includes a pad formed of an air impermeable material defining an air distribution chamber. The air distribution chamber has a plurality of longitudinal passages extending between transverse plenum chambers at each end of the pad, and an air inlet connects to the plenum chamber at the foot of the pad. The longitudinally extending air passages are defined by lower rounded surfaces which have openings or apertures therein spaced from the body of an individual and arranged to direct cool air onto the individual in a jet action.

A preferred source of cool air is a refrigeration or air conditioning system which includes a blower to cause the air to flow in heat exchange with the refrigeration system, and means for delivering the cooled air from the refrigeration system to the air distribution chamber inlet. A coverlet formed of a porous material has a pouch or pocket to receive the pad and air discharged from the apertures of the distribution chamber is diffused slightly by the porous material of the coverlet to keep the cool air flow from impacting an objectionable jet streams on the body of a user. Although some diffusing of the jet stream is desirable, an important part of this concept of cooling is to rely heavily upon the velocity of the air stream to enhance the cooling effect,

thereby reducing the need for temperature depression and additional BTU cooling capacity.

An object of the present invention is to provide an improved cooling cover for a human body or individual which is effective for cooling the individual while sleeping or resting.

Another object is to provide an improved cooling cover for a human body which is relatively simple in construction, reasonable in cost, and can be operated with a portable power supply.

A further object is to provide an improved cooling cover for sleeping in hot environments which is efficient by exposing the body skin to a meaningful air velocity, but at the same time does not expose the user to jets of uncomfortably cool air.

DESCRIPTION OF THE DRAWINGS

These and other objects and advantages are hereinafter set forth and explained with reference to the drawings wherein:

FIG. 1 is an elevational view, partly schematic, of the improved cooling apparatus of the present invention including an outer coverlet and an inner pad contained therein having an air distribution chamber.

FIG. 2 is a view of the underside of the inner pad forming the air distribution chamber of the present invention.

FIG. 3 is a elevational view of the inner pad taken along line 3—3 in FIG. 2.

FIG. 4 is a sectional view of the inner pad taken along line 4—4 in FIG. 2.

FIG. 4A is a sectional view of the inner pad taken along line 4A—4A in FIG. 2.

FIG. 5 is a sectional view of the inner pad taken along line 5—5 in FIG. 2 to illustrate the air distribution chamber apertures.

FIG. 6 is a plan of the underside of the outer coverlet having pockets to receive the pads.

FIG. 7 is a sectional view of the coverlet taken along line 7—7 of FIG. 6 with the inner pad shown in broken lines.

FIG. 8 is a sectional view of the coverlet taken along line 8—8 of FIG. 6.

BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENT

The improved cooling cover of the present invention is indicated generally at 10 in FIG. 1 covering an individual or person 12 positioned on a mattress 13 of bed 14. Cooling cover 10 includes a pair of inner pads 16 positioned within an outer coverlet 18. Pads 16 form air distribution chambers and each pad 16 as shown in FIGS. 2-5 is preferably formed of an air impermeable heat bondable material such as polyethylene, polyvinylchloride, or other similar material.

Outer coverlet 18 as shown in FIGS. 6-8 includes an outer sheet 17 which may be formed, if desired, of an air permeable or porous material such as cotton; and an inner spaced sheet 19 which is always formed of an air permeable or porous material. Inner sheet 19 which is normally placed adjacent the body of a user is secured at one end 19A, sides 19B and intermediate portion 19C to sheet 17. The other end 19D of sheet 19 is open and spaced from sheet 17 thereby to define a pair of identical porous pockets or pouches 20 arranged in side-by-side relation. Each pouch 20 receives an inner pad 16 within open end 19D. A source of cool air such as cool

air generator 21 is connected to a flexible hose or conduit 24 and has a suitable blower for delivering cool air to inner pads 16.

Each inner pad 16 which forms the air distribution chamber as shown in FIGS. 2, 3 and 4, is formed of two sheets of air impermeable material 22 as set forth above which are bonded together at their outer edges 22A. Also, intermediate portions 22B are suitably joined, as by bonding, to form a plurality of longitudinally extending air passages 26 extending from transversely extending plenum chambers 28 at each end. An air inlet 30 is positioned at the end of each pad 16 in communication with plenum chamber 28 to supply air to air passages 26.

Coverlet 18 has an end marginal portion 17A which extends beyond upper sheet 19 and beyond porous pouches 20 in which inner pads 16 are positioned. End portion 17A may be folded under the feet of individual 12 or be tucked under mattress 13 on bed 14 to provide a selective positioning of pads 16 and the air distribution chambers thereof on the individual. Coverlet 18 has suitable openings 29 and 31 to receive flexible hose 24 for connection to inlet 30 thereby to provide cool air to air passages 26 from cool air generator 21. Snap fasteners 33 on outer sheet 17 may engage interfitting fasteners 35 on pads 16 to hold pads 16 in place within pockets 20.

Each of the longitudinally extending air passages defines a lower rounded surface which is provided with a plurality of apertures 34 positioned as best shown in FIG. 5 so that the resting of inner pad 16 on the individual does not block the flow through any of the apertures 34 since apertures 34 are spaced from the body of the individual. Inner pad 16 is inflatable and a generally uniform pressure is provided. A predetermined arrangement of apertures 34 which form air orifices for pad 16 directs the air to predetermined areas of the body. Thus, a non-uniform distribution of apertures 34 permits a relatively high cooling efficiency.

It has been discovered that the jetting of the cool air through the apertures 34 at a velocity of not less than thirty feet per second results in very substantially improved cooling as compared to air diffusion through a sheet or cover. Also, each pad 16 would have approximately one hundred (100) one-eighth inch diameter apertures 34.

Further, it has been found that a cooling capacity of cool air generator 21 should be approximately 650 BTU/hour per person being cooled. This will provide an ambient air cooling at the source between 20° and 25° F. with a reduction of 18° F. at the body of the individual for cooling with ambient air temperature above 90° F. The air flow onto an individual is preferred to be in the range of 20 to 35 cubic feet per minute. A pressure of 0.4 to 0.9 inches of water is maintained in pad 16 to control the optimum air velocity and to support the shape of pad 16. An electric power consumption of between 130 and 175 watts per person allows a 300 to 350 watt generator to service a double unit as shown in FIG. 6.

It is suggested that the evaporator coil in the cool air generator be located above the vertical midpoint of the condenser unit so that gravity causes condensed moisture from the evaporator coil to flow to the hot condenser coil for evaporation and thus to increase the efficiency of the unit under high humidity conditions.

While the preferred embodiment of coverlet 18 is illustrated in FIGS. 6-8 as having a pair of pouches 20 for a pair of pads 16, it is to be understood that a single

pad 16 and single porous pouch 20 could be provided if desired.

While preferred embodiments of the present invention have been illustrated in detail, it is apparent that modifications and adaptations of the preferred embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention as set forth in the following claims.

What is claimed is:

1. A generally rectangular cooling cover adapted to be positioned over a human body in a prone position; said cooling cover comprising:

a coverlet having an outer sheet, an inner porous pouch attached to the outer sheet, and an inner pad within the porous pouch;

said inner pad including a pair of upper and lower sheets formed of an air impermeable material with the upper sheet adjacent the coverlet and the lower sheet adjacent the porous pouch, said sheets secured to each other along their outer edges to form an air distribution chamber therebetween, and secured to each other along a plurality of parallel intermediate portions extending lengthwise between the ends of the sheets for a major portion thereof to form a plurality of separate longitudinally extending air passages therebetween having lower rounded surfaces, a plenum chamber extending transversely of the pad at each end thereof in fluid communication with said longitudinally extending air passages; and

a cool air inlet at one end of said inner pad, said coverlet having an opening therein in alignment with said inlet of said pad adapted to receive a source of cool air for connection to said inlet;

said lower rounded surfaces having a plurality of apertures along the length thereof at locations other than the lowermost portion of said rounded surfaces and in fluid communication with said longitudinally extending passages whereby cool air may be discharged as small jets through said apertures at an angular relation to a vertical plane for diffusing through the porous pouch to contact a large area of the body cooled.

2. A cooling cover as set forth in claim 1 wherein said outer sheet of said coverlet has fasteners thereon adjacent the corners of said pad, and said pad has interfitting fasteners thereby to releasably secure said pad within the pocket of said coverlet.

3. A cooling cover as set forth in claim 1 wherein said outer sheet of said coverlet and said pouch have aligned openings therein adapted to receive a flexible hose from said source of cool air for connection to said cool air inlet of said pad, thereby to supply cool air to said pad.

4. A cooling cover as set forth in claim 1 wherein said upper and lower sheets of said inner pad are formed of heat bondable plastic material.

5. Air conditioning means for a human body comprising:

a general rectangular cooling cover adapted to be positioned over the human body in a prone position, said cooling cover including a coverlet having an outer sheet, an inner porous pouch attached to the outer sheet, and an inner pad within the porous pouch; said inner pad including a pair of upper and lower sheets formed of an air impermeable material with the upper sheet adjacent the coverlet and the lower sheet adjacent said porous pouch, said sheets

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secured to each other along the outer edges to form an air distribution chamber therebetween, and secured to each other along a plurality of parallel intermediate portions extending lengthwise between the ends of the sheets for a major portion thereof to form rounded surfaces defining a plurality of separate longitudinally extending air passages;

a plenum chamber extending transversely of said pad at each end thereof in fluid communication with said longitudinal extending air passages, said rounded surfaces having a plurality of apertures therein for discharging cool air therethrough as small jets for diffusing through the air permeable porous pouch for contacting the human body, said

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apertures being arranged in a non-uniform manner with air being discharged therefrom at a velocity in a range between 30 and 50 feet per second;

a cool air inlet at one end of said inner pad in fluid communication with the associated plenum chamber at said one end, said coverlet having an opening adjacent said cool air inlet;

a source of cool air; and

means extending through said opening in said coverlet to said inlet to connect the source of cool air to said air inlet for inflating the inflatable pad and providing air to said apertures for discharge therefrom, said source of cool air having a capacity of approximately 650 BTU/hour per person.

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United States Patent [19]

Sandhaus

[11] Patent Number: 4,807,644

[45] Date of Patent: Feb. 28, 1989

[54] TEMPERATURE-REGULATING SURGICAL DRAPE

[75] Inventor: Jeffrey J. Sandhaus, Astoria, N.Y.

[73] Assignee: Vastech Medical Products Inc., New Brunswick, N.J.

[21] Appl. No.: 13,773

[22] Filed: Feb. 12, 1987

[51] Int. Cl.⁴ A61F 13/00

[52] U.S. Cl. 128/849; 128/853

[58] Field of Search 128/132 D, 132 R, 402, 128/403, 134, 399; 604/113, 114; 219/212, 523

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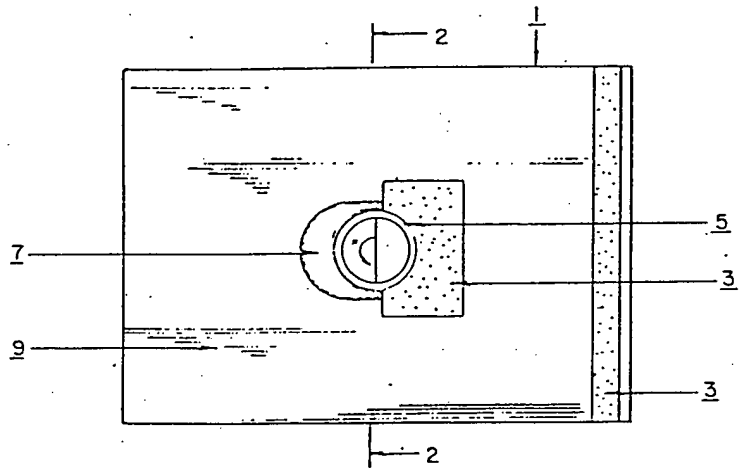
3,951,127 4/1976 Watson et al. 128/403 X

4,316,456 2/1982 Stoneback 128/132 D
4,413,624 11/1983 Snow 128/402 X
4,573,447 3/1986 Thrash et al. 128/403 XPrimary Examiner—Robert A. Hafer
Assistant Examiner—Kevin G. Rooney
Attorney, Agent, or Firm—Lerner, David, Littenberg, Krumholz & Mentlik

[57] ABSTRACT

Temperature regulating surgical drapes are disclosed for use in conducting surgical procedures including a drape body with an opening adapted to expose only the specific body portion during surgery and including heat generating or cooling elements affixed to the drape at a localized position surrounding the opening to maintain that body portion at a specified temperature during surgery.

28 Claims, 2 Drawing Sheets



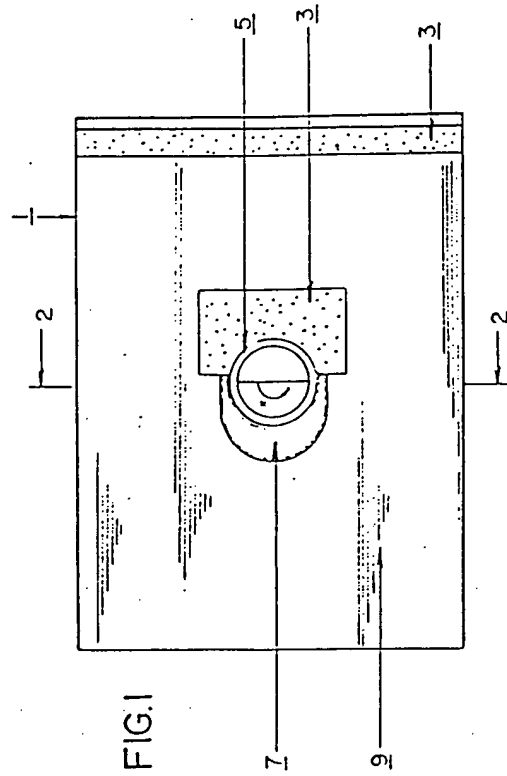


FIG. 1

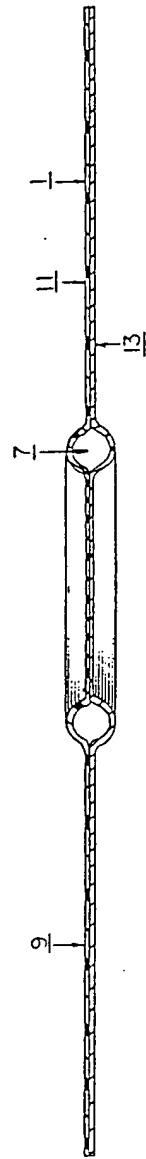


FIG. 2

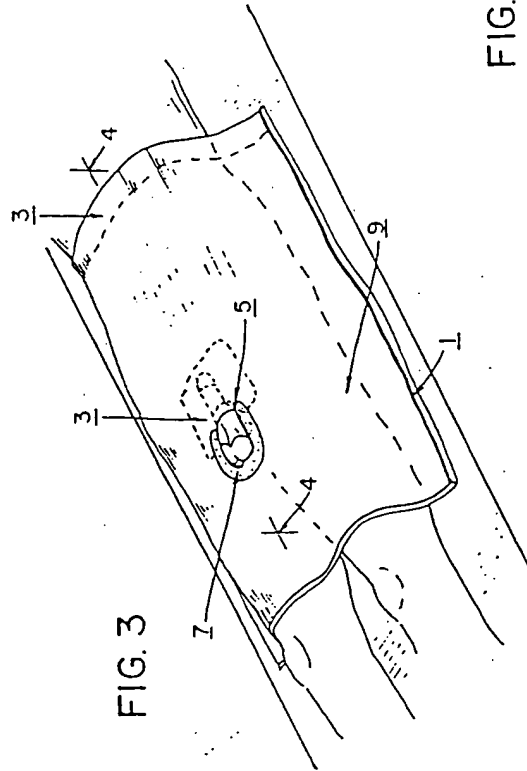
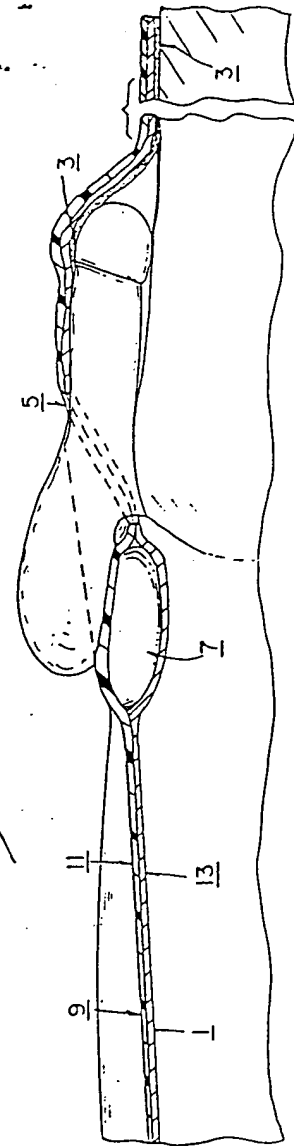


FIG. 4



TEMPERATURE-REGULATING SURGICAL DRAPE

FIELD OF THE INVENTION

This invention relates generally to fenestrated surgical drapes, temperature-regulating surgical devices, and more specifically, to self-warming or self-cooling surgical drapes for use in scrotal surgery.

BACKGROUND OF THE INVENTION

Most surgical procedures require the use of fenestrated drapes which allow the surgeon access to the appropriate body region while simultaneously covering the rest of the body. The use of surgical drapes is not confined to humans. They are frequently used in animal surgery whenever it is desirable to cover all of the body save the operating field. Such drapes today are usually disposable and water repellant. They can be attached to the body by adhesive to prevent sliding during surgery. Drapes of this sort are usually best-suited to use on relatively flat, smooth portions of the body such as the abdomen.

In performing vasectomy procedures the surgeon operates on the patient's scrotum. Such procedures present special surgical problems. The male reproductive organs' shapes are not ones to which surgical drapes readily conform. The scrotum tends to thicken and contract when cooled during exposure. This causes the testes and sperm ducts to move upward toward the groin, making surgery in this region difficult. Scrotal surgery is normally performed with the patient lying on his back and his penis placed against his abdomen with its lower surface facing upward. This is not a stable position and the penis frequently enters into the surgical field.

Fenestrated surgical drapes are manufactured with openings which allow access to the surgical field. They can be produced in a variety of forms and with a variety of sizes and shapes of surgical openings. Normally the surgical drape is placed above the surgical zone. When operating on irregularly shaped regions it may be advantageous to position the drape in a different manner. It is suggested that when surgery is performed in the scrotal region the scrotum be passed through a hole in the drape and placed above the drape. This orientation has two benefits; it isolates the scrotum from the body, and it locates the penis under the drape so as to keep it from intruding into the field of surgery.

The scrotum contracts or relaxes in reaction to changes in temperature. When cooled, it contracts and its surface thickens, pulling the testes and sperm ducts upward toward the body. Such changes make surgery more difficult and so it is desirable to keep the scrotum warm to encourage the desirable relaxation response. Presently, surgical aids for maintaining a desired temperature include heat lamps, electrical heating pads, and sterile wet toweling. All require the use of expensive reusable equipment, which must be sterilized before later use and which can clutter or obstruct the surgical field.

Pouchlike heating or cooling devices containing separated chemical reactants, which only change temperature when manipulated so as to mix those reactants by rupturing at least one internal pouch are admittedly well-known in the art. See, for example: U.S. Pat. Nos. 4,080,953 (Mitchell); 3,854,156 (Williams); and 3,175,558 (Cailouette). Similarly, fenestrated surgical

drapes are well-known; see U.S. Pat. No. 4,316,456 (Stoneback). Williams, the closest to these patents to the instant invention, teaches only the use of a chemically-activated temperature regulating device in a combination mattress and blanket for transporting infants. It does not contemplate use in surgery. The now-expired Cailouette patent teaches the use of a chemically-activated temperature-regulating pack surrounded by a disposable outer cover, but does not contemplate use in surgery. The present invention successfully combines the temperature-control function of the already-known thermal pouches with the field-isolating function of surgical drapes in a low-cost, disposable structure, while simultaneously facilitating unimpeded access to the surgical field.

The present invention solves both the problems of scrotal contraction and intrusion of the penis into the surgical field.

OBJECTS AND STATEMENT OF THE INVENTION

It is therefore an object of the present invention to provide a surgical drape which allows maintenance of the surgical field within a preselected temperature range.

It is another object of the present invention to provide a surgical drape which will permit maintenance of the scrotum within a preselected temperature range.

It is a further object of the present invention to provide a surgical drape which, while isolating and exposing the scrotum, serves to keep the penis from intruding into the surgical field.

In one advantageous embodiment of an apparatus employing the instant invention, the temperature control and restraining functions are achieved by providing the following. A multilayered surgical drape with a centrally located opening of size slightly larger than the scrotum is employed. A strip of suitable adhesive runs along a portion of the perimeter of the lower surface of the drape. Another strip may be located adjacent to the edge of the drape's central opening. Both of these strips can be covered with plastic sheeting until use.

A thermal bag is fixably secured to the drape in such an orientation as to place its main portion nearest the patient's feet. The thermal bag lies underneath the patient's scrotum. The scrotum passes through the drape's opening and rests above the portion of the drape containing the thermal bag. The penis is kept out of surgical field (its top surface is held against the patient's abdomen,) and is medially located above the body and beneath the drape. The drape is further restrained by the aforementioned adhesive strips found on its lower surface.

The thermal bag attached to the drape is a flexible, leak-proof sack containing a primary reactant and a second smaller internal bag. The smaller internal bag is constructed such that vigorous bending or squeezing of the outer bag will cause the smaller internal bag to rupture. The internal bag contains a secondary reactant which, upon contact with the primary reactant disposed throughout the external bag, experiences either an exothermic or endothermic reaction which changes the temperature of the assembly. The primary and secondary reactants can be selected to cause the surgical field to achieve a temperature within a predetermined range. The aforementioned quality whereby vigorous bending or squeezing ruptures the internal bag but not the exter-

nal bag is called "manipulable rupturability." A manipulably rupturable bag must be constructed to protect against accidental rupture if dropped or mishandled, while not requiring undue effort to deliberately rupture the bag.

In another advantageous embodiment the drape's opening is constructed so that its perimeter elastically conforms to the portion of the scrotum passing through it. This facilitates isolating the surgical field.

In actual operation the drape is removed from its sterile container and the bag is manipulated to break the internal bag, mixing the reactants and as a result of either an endothermic or exothermic reaction changing the bag temperature. The plastic sheeting covering the adhesive strips is removed and the fresh adhesive exposed. The drape is placed on the patient's torso; the penis is held under the drape against midline of the abdomen. The drape should be oriented so that the median of the bag is closest to the patient's legs. The scrotum is passed through the opening and placed atop the thermal bag.

Two advantages pertain to users of this invention. First, the scrotum can be kept warm by choosing reactants which, when combined, release heat. This will cause the scrotum to relax and descend, facilitating access to the organs therein.

Second, the penis will be kept from shifting into the operating field because it is held beneath the surgical drape, itself held immobile by the adhesive strips on its lower side.

The foregoing objects, features and advantages of the present invention will become apparent from the following description of preferred embodiment in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top elevational view of one embodiment of the present invention.

FIG. 2 is a cross-sectional view of one embodiment of the present invention as seen along line 2—2 in FIG. 1.

FIG. 3 is a perspective view showing one embodiment of the present invention as used in surgery.

FIG. 4 is a cross-sectional view as seen along line 4—4 in FIG. 3.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

Referring now to the drawings and, in particular, to FIGS. 1-4, there is depicted one embodiment of an apparatus in accordance with the present invention.

A surgical drape assembly 1, having an opening 5, is located in the drape surface 9. Adhesive strips 3 are located on a portion of the underside of the drape surface 9. A thermal bag 7 containing a temperature regulating means which is activated by selective manipulation of the thermal bag 7 is fixed about opening 5. The thermal bag 7 has the approximate shape of a semiannular section subtending an angle x about the center of a toroid describing an annulus about said opening 5, said angle x being between 0 and 360 degrees. This shape is merely one of a myriad of other possible forms which will work equally well, such as discs, oblongs or polygons, either enclosing or adjacent to the opening 5. The thermal bag 7 is fixed between an upper drape surface 11 and a lower drape surface 13 as shown in FIG. 3. The thermal bag can also, if desired, be attached only to a surface of the drape 9.

The surgical drape assembly 1 is aligned so that the patient's scrotum passes through the opening 5 and rests upon the portion of the assembly containing the thermal bag 7. The patient's penis rests underneath the drape assembly 1 and is securely held by contact with a portion of an adhesive strip 3. Another adhesive strip 3 secures the drape assembly 1 to the patient's body. The scrotum, passing through the opening 5 rests on the upper drape surface 11 atop the thermal bag 7. The bag is fixably held between the upper drape surface 11 and the lower drape surface 13. One adhesive strip 3 attaches the penis to the lower drape surface 13 and another adhesive strip 3 attaches the lower drape surface to the patient's body.

The invention is employed using the following procedure: The thermal bag 7 is specifically manipulated so as to activate its temperature-regulating means. Such temperature-regulating bags are well known and often bag ("first bag") contains a primary reactant and an inner, rupturable bag ("second bag,") contains a secondary reactant. The second bag breaks only after specific manipulation of the first bag. The reactants then mix and chemically combine in the still-intact first bag. The reactant are chosen so that the chemical reaction which results from their mixture causes the contents of the bag to reach from their mixture causes the contents to the bag to reach a preselected temperature and maintain that temperature for some period. Once the thermal bag 7 is specifically manipulated the scrotum is passed through the openings 5 and placed atop the upper drape surface 11 above the thermal bag 7. The adhesive strips 3 are pressed against the penis and body to keep the penis and drape from shifting.

It is also possible to use the instant invention in operations involving body parts other than the scrotum, whenever it is desirable to maintain the surgical field at a predetermined temperature.

Although a particular illustrative embodiment of the present invention has been described herein, the present invention is not limited to this embodiment. Various changes, substitutions and modifications may be made thereto by those skilled in the art without departing from the spirit or scope of the invention defined by the appended claims.

I claim:

1. A temperature-regulating surgical drape for use in conducting surgical procedures on a predetermined body portion of a patient comprising a substantially planar drape body including an opening adapted to expose only said predetermined body portion during said surgical procedure, and means for generating heat affixed to said drape body at a localized predetermined location surrounding at least a portion of said opening for maintaining said predetermined body portion at a predetermined elevated temperature during said surgical procedure.

2. The temperature-regulating surgical drape of claim 1 wherein said opening comprises a circular opening.

3. The temperature-regulating surgical drape of claim 2 wherein said portion of said opening comprises approximately a 180° portion about said circular opening.

4. The temperature-regulating surgical drape of claim 1 wherein said drape body comprises a first layer and a second layer, and wherein said means for generating heat is disposed between said first and second layers.

5. The temperature-regulating surgical drape of claim 1 wherein said means for generating heat comprises a plurality of chemical reactants adapted to maintain said

body portion at said predetermined temperature by reacting with each other upon their admixture.

6. The temperature-regulating surgical drape of claim 1 wherein said drape body includes an upper surface and a lower surface, said lower surface including adhesive means located adjacent to said opening for maintaining a body portion other than said predetermined body portion in position below said drape during said surgical procedure.

7. The temperature-regulating surgical drape of claim 6 wherein said adhesive portion comprises a first adhesive portion, wherein said bottom surface of said drape body includes a second adhesive portion for adhesively securing said surgical drape to said body during said surgical procedure.

8. A temperature-regulating surgical drape for use in conducting surgical procedures on the male scrotum comprising a drape body including an opening adapted to expose only said male scrotum while covering the remainder of said body including the penis during said surgical procedure, and means for generating heat affixed to said drape body at a localized predetermined location surrounding at least a portion of said opening so as to be disposed in contact with said male scrotum during said surgical procedure and thereby selectively maintaining said male scrotum at a predetermined elevated temperature during said surgical procedure.

9. The temperature-regulating surgical drape of claim 8 wherein said opening comprises a circular opening.

10. The temperature-regulating surgical drape of claim 9 wherein said means for generating heat is disposed circumferentially around a portion of said circular opening extending approximately 180° about said circular opening.

11. The temperature-regulating surgical drape of claim 8 wherein said drape body comprises a first layer and a second layer, and wherein said means for generating heat is disposed between said first and second layers.

12. The temperature-regulating surgical drape of claim 8 wherein said drape body includes an upper surface and a lower surface, and including adhesive means on said lower surface of said drape body adjacent to said opening so as to maintain said penis in a fixed position during said surgical procedure.

13. The temperature-regulating surgical drape of claim 12 wherein said adhesive means comprises first adhesive means, and including a second adhesive means on said lower surface of said drape for maintaining said surgical drape in position with respect to said body during said surgical procedure.

14. The temperature-regulating surgical drape of claim 8 including activation means for selectively activating said means for generating heat during said surgical procedure.

15. A temperature-regulating surgical drape for use in conducting surgical procedures on a predetermined body portion of a patient comprising a substantially planar drape body including an opening adapted to expose only said predetermined body portion during said surgical procedure, and means for cooling affixed to said drape body at a localized predetermined location surrounding at least a portion of said opening for maintaining said predetermined body portion at a predetermined reduced temperature during said surgical procedure.

16. The temperature-regulating surgical drape of claim 22 wherein said opening comprises a circular

opening, and wherein said means for cooling surrounds at least a portion of said opening.

17. The temperature-regulating surgical drape of claim 23 wherein said portion of said opening comprises approximately a 180° portion about said circular opening.

18. The temperature-regulating surgical drape of claim 15 wherein said drape body comprises a first layer and a second layer, and wherein said means for cooling is disposed between said first and second layers.

19. The temperature-regulating surgical drape of claim 15 wherein said means for cooling comprises a plurality of chemical reactants adapted to maintain said body portion at said predetermined reduced temperature by reacting with each other upon their admixture.

20. The temperature-regulating surgical drape of claim 15 wherein said drape body includes an upper surface and a lower surface, said lower surface including adhesive means located adjacent to said opening for maintaining a body portion other than said predetermined body portion in position below said drape during said surgical procedure.

21. The temperature-regulating surgical drape of claim 20 wherein said adhesive portion comprises a first adhesive portion, and wherein said bottom surface of said drape body includes a second adhesive portion for adhesively securing said surgical drape to said body during said surgical portion.

22. A temperature-regulating surgical drape for use in conducting surgical procedure on the male scrotum comprising a drape body including an opening adapted to expose only said male scrotum while covering the remainder of said body including the penis during said surgical procedure, and means for cooling affixed to said drape body at a localized predetermined location surrounding at least a portion of said opening so as to be disposed in contact with said male scrotum during said surgical procedure and thereby selectively maintaining said male scrotum at a predetermined reduced temperature during said surgical procedure.

23. The temperature-regulating surgical drape of claim 22 wherein said opening comprises a circular opening.

24. The temperature-regulating surgical drape of claim 23 wherein said means for cooling is disposed circumferentially around a portion of said circular opening extending approximately 180° about said circular opening.

25. The temperature-regulating surgical drape of claim 22 wherein said drape body comprises a first layer and a second layer, and wherein said means for cooling is disposed between said first and second layers.

26. The temperature-regulating surgical drape of claim 22 wherein said drape body includes an upper surface and a lower surface, and including adhesive means on said lower surface of said drape body adjacent to said opening so as to maintain said penis in a fixed position during said surgical procedure.

27. The temperature-regulating drape of claim 26 wherein said adhesive means comprises first adhesive means, and including a second adhesive means on said lower surface of said drape for maintaining said surgical drape in position with respect to said body during said surgical procedure.

28. The temperature-regulating surgical drape of claim 22 including activation means for selectively activating said means for cooling during said surgical procedure.

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,807,644
DATED : February 28, 1989
INVENTOR(S) : Jeffrey J. Sandhaus

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, line 13, delete "surge ion" and insert therefor
--surgeon--.

Column 1, line 24, delete "surge ion" and insert therefor
--surgeon--.

Column 5, line 12, following "portion," insert --and--.

Column 6, line 4, delete "23" and substitute therefor --16--.

Column 6, line 30, delete "procedure" and substitute therefor
--procedures--.

Signed and Sealed this
Twelfth Day of September, 1989

Attest:

DONALD J. QUIGG

Attesting Officer

Commissioner of Patents and Trademarks



US005125238A

United States Patent [19]

Ragan et al.

[11] Patent Number: 5,125,238

[45] Date of Patent: Jun. 30, 1992

[54] PATIENT WARMING OR COOLING BLANKET

[75] Inventors: Raymond G. Ragan; James G. Stephenson; Charles L. Zuck, all of Marshall, Mich.

[73] Assignee: Progressive Dynamics, Inc., Marshall, Mich.

[21] Appl. No.: 692,572

[22] Filed: Apr. 29, 1991

[51] Int. Cl. A47C 27/08

[52] U.S. Cl. 62/259.3; 165/46; 126/204; 128/400; 5/423

[58] Field of Search 62/259.3, 261; 128/400; 165/46; 5/284, 423, 469; 126/204

[56] References Cited

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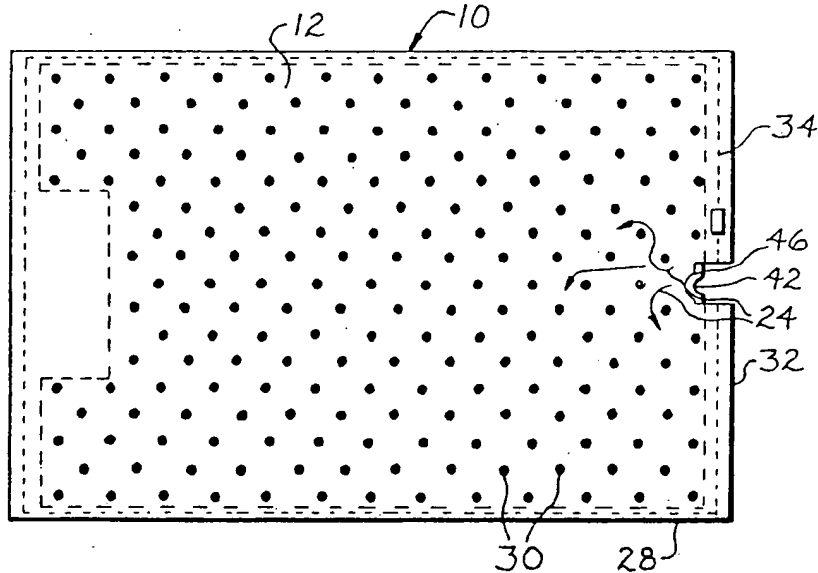
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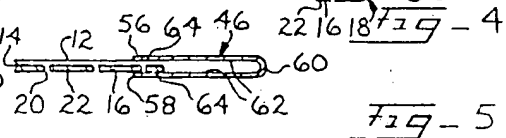
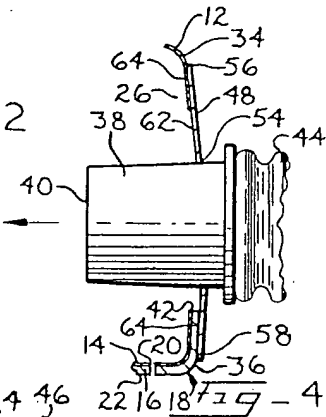
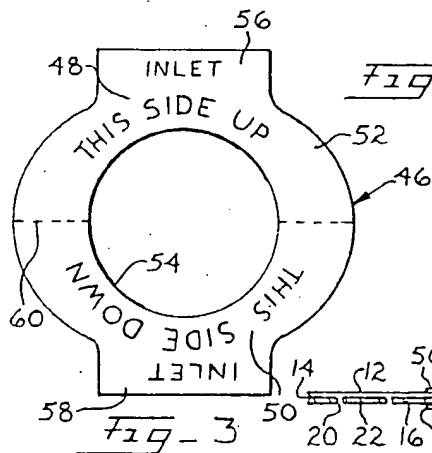
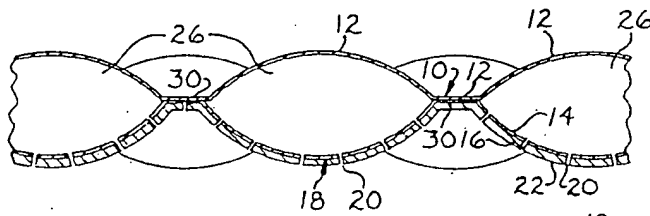
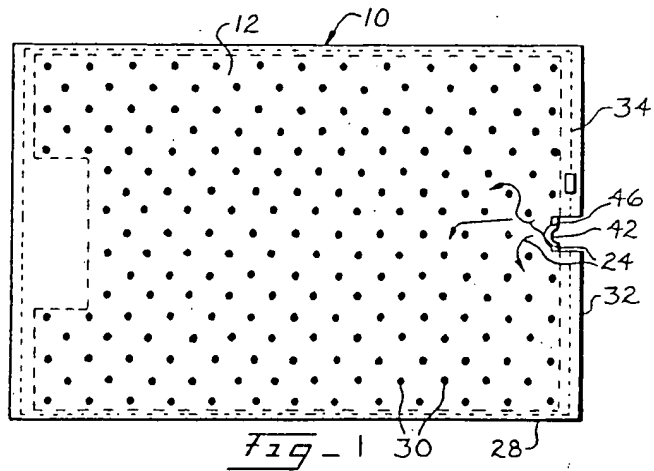
Primary Examiner—Albert J. Makay
Assistant Examiner—William C. Doerfler
Attorney, Agent, or Firm—Beaman & Beaman

[57] ABSTRACT

A disposable patient heating or cooling blanket having three layers of flexible sheeting two of which form an air chamber, the third of which is a comfortable layer for contact with the patient and which, having a greater friction characteristic, aids in keeping the blanket in place on the patient. The patient is bathed in conditioned air through a multiplicity of orifices in the bottom layers of the blanket and the size and location of the orifices are such that sufficient pressure exists within the blanket to prevent crimping blockage and to insure a uniform flow of air through the orifices throughout the blanket area. Conditioned air is introduced horizontally through an external nozzle which is inserted into a low cost foldable fitting plate bonded to the blanket which permits the blanket to be concisely folded and packaged.

9 Claims, 1 Drawing Sheet





PATIENT WARMING OR COOLING BLANKET

BACKGROUND OF THE INVENTION

Medical care providers have long recognized the need to provide warmth and cooling directly to patients as part of their treatment and therapy. The relatively recent proliferation of mobile emergency medical facilities as an adjunct to fire departments and the expansion of clinical facility services in the community has increased the number of sites where such treatments must be given. Consequently, there has evolved a need for an inexpensive disposable patient thermal control blanket which will provide a distributed air flow while maintaining sufficient pressure in the blanket to prevent blockage of the flow due to the blanket folding or crimping.

FIELD OF THE INVENTION

The present application relates to a patient warming or cooling blanket which employs a bath of temperature controlled air applied to the patient rather than utilizing direct or indirect contact with a heat exchanger.

DESCRIPTION OF RELATED ART

Devices of the type described above are well known in the art, for example U.S. Pat. No. 2,093,834 discloses of a mechanism for providing localized air conditioning by means of an inflatable covering constructed of plurality of tubular enclosures of porous material in conjunction with a quilted covering. Devices of this construction rely on a recirculating cooling or heating medium and transfer heat mainly through contact with the blanket surfaces. This patented device as well as those of U.S. Pat. Nos. 2,601,189 and 4,572,188 which are also of such essentially tubular or corrugated construction have the disadvantage that they are longitudinally rigid, relatively uncomfortable, have a high profile, and due to the complexity of devices of this type, they are relatively expensive to construct. U.S. Pat. No. 2,093,834 shows a construction which is susceptible to tube wall compression which constricts the flow path and increases internal pressure resulting in flow restriction and rigidity due to the entrapment of air within the device. The construction of the devices of U.S. Pat. Nos. 2,601,189 and 4,572,188 include lateral passages to adjacent tubes which do not fully alleviate the tube compression flow restriction problem and are more expensive to fabricate than the instant invention by virtue of their complex construction.

OBJECTS OF THE INVENTION

In view of the foregoing shortcomings in pneumatic temperature control patient blanket fabrication, it is an object of the invention to provide a disposable blanket for use in patient warming and cooling applications which is simple to operate, easy to construct, economical to manufacture and concisely storable.

A further object of the invention is to provide a pneumatic blanket which employs materials and structural elements which are comfortable to the patient with whom they contact.

An additional object of the pneumatic patient blanket is to provide an even, pleasant and healthy flow of air uniformly over the covered area regardless of where the blanket air chamber may be compressed.

SUMMARY OF THE INVENTION

The invention pertains to disposable heating and cooling patient blankets. An external air conditioning unit provides low pressure heated or dehumidified and cooled air through a flexible hose having a supply nozzle. Conditioned air is introduced into the blanket pneumatic chamber by means of the supply nozzle which inserts into an inlet port through a low-cost folding cardboard fitting plate mounted on the edge of the blanket.

The folding cardboard fitting plate has a folded storage mode to permit the blanket to be folded into a compact mass for storage. In its open operative mode the fitting plate is essentially planar having an opening which is sized to snugly receive the supply nozzle horizontally through the blanket edge directly into a pneumatic flow chamber thereby avoiding opposite wall obstructions of the supply nozzle airflow.

The pneumatic flow chamber is constructed of, and defined by, the interface of two polyethylene sheets heat bonded together at their perimeters and at a plurality of staking points in a single step of the assembly process. Air flow through the blanket is enhanced by the creation of fully redundant flow paths around the staggered dot staking pattern which is distributed throughout the blanket area. A layer of non-woven wood pulp airlaid material is adhesively bonded to the bottom sheet of polypropylene thereby forming a laminated layer and both the bottom sheet of polyethylene and airlaid material are perforated by an array of selectively sized orifices. The orifices are distributed in a regular pattern throughout the area bounded by the pneumatic chamber parameter and allow the emission of an even, gentle air stream from the blanket bottom and are of such size that the blanket will be pressurized enough to hold its shape and resist crimping of the air flow due to normal compressive forces being applied to the blanket. The airlaid material rests comfortably against the patient bathing the patient in the air emitted from the orifices and helps keep the blanket from sliding off the patient because of its high frictional characteristics.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the invention may be clearly understood, it will now be described, by way of example, with reference to the accompanying drawings, wherein:

FIG. 1 is a plan view of the patient blanket in accord with the invention,

FIG. 2 is an enlarged, cross-sectional, detail elevation view of the blanket showing the pneumatic chamber between staking points as well as the relationship of the several blanket layers in accord with the invention,

FIG. 3 is an elevational view of the folding cardboard fitting plate in accord with the invention shown in the open or unfolded mode,

FIG. 4 is an enlarged, elevational, detail sectional view of the folding cardboard fitting plate air inlet connection with an external air supply nozzle inserted therein in accord with the invention, and

FIG. 5 is an enlarged, elevational, detail view of the cardboard fitting plate as attached to the blanket in accord with the invention and shown in the folded storage condition.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the invention, a three layer construction is employed to form the patient blanket 10 with two layers forming an air chamber and a third layer providing a comfortable surface for contact with the patient. It will be obvious to a person familiar in the art, that any of a number of flexible sheeting materials can be used for the upper flexible sheet 12 and lower flexible sheet 14, but in the preferred embodiment for economy, strength and flexibility considerations 1.5 mil thickness polyethylene sheeting was selected. Simple, economical assembly of the blanket begins when the .015 inch thick layer of non-woven fibrous layer of wood pulp airlaid material 16 is adhesively bonded to the lower side of the 1.5 mil thickness lower flexible sheet 14 forming the laminate assembly 18, as shown in FIG. 2. This fibrous layer 16 provides a comfortable surface in contact with the patient and its high frictional characteristic helps keep the blanket in place on the patient. A material of this type is available under the trademark "AIRTEX" from the Fiberware Corporation. The laminate assembly 18 is then perforated with specifically sized orifice holes 20 by means of a punch plate. The orifice size is determined by the volume flow characteristics of the air source and by the following formula:

$$Q = K \cdot A \cdot \sqrt{\Delta P}$$

Where Q is the air flow rate in cubic feet per minute. K is a constant, A is the area of the orifices and ΔP is the differential pressure in inches of water at standard room conditions. From test results it was determined that for proper flow and inflation K should be 11.718, A should equal 0.001 square inches for each square inch of blanket which will produce 0.035 inch diameter orifices on 1 inch centers and ΔP is 0.25 inches of water.

The sizing of the orifices 20 by this method assures sufficient inflation to minimize crimping of the blanket while providing continuous air flow to the lower surface 22 that is both evenly distributed and above the minimum flow quantity required. The problems associated with compressing or crimping the blanket are also alleviated through the invention's incorporation of a multiplicity of redundant flow paths as shown by the arrows 24 within the pneumatic flow chambers 26 as shown in FIG. 1 due to the inflation of the blanket.

Subsequent to the lower layer lamination and orifice perforation, the upper flexible sheet 12 is laid upon the laminated assembly 18 and the periphery 28 of the two polyethylene layers are heat sealed together. In the same process step, the two flexible sheets are also staked together in a staggered pattern of one inch diameter heat sealed staking bonds or welds 30 throughout the area within the periphery seal. This staking creates the redundant flow paths 24 feature of the invention as well as serving the dual purposes of reducing stresses to the inflated structure through reducing the radius of the chambers 26, and through the same mechanism reducing the blanket inflated thickness while assuring flow distribution and continuity across the lower surface 22 of the blanket.

The preferred air inlet location is through a fitting plate on the blanket edge 32 intermediate the upper flexible sheet first end 34 and the lower flexible sheet first end 36. In this blanket edge center, a semicircular cut is made through the laminated assembly 18 and the upper flexible sheet 12. When the blanket is inflated,

these semicircular cuts form an essentially horizontal circular air inlet port 42. By horizontal insertion of an air supply nozzle through the fitting plate into the blanket air flow is unrestricted by blanket film members pressing against the nozzle opening, and furthermore, there is no need to support the nozzle's weight. The conditioned air is introduced through a flexible hose 44 having a frustoconical end nozzle 38 converging towards the nozzle end 40.

The fitting plate 46, in accord with the invention, is best shown in FIGS. 3, 4 and 5. The plate 46 is fabricated of a low cost, foldable material with an exterior surface suitable for direct labeling. In the preferred embodiment, cardboard was selected as meeting the aforementioned criteria as well as being an inexpensive and easy to print material. The fitting plate 46 is an elongated member having a first end 48 and a second end 50 each with an extension and having a circular central portion 52 intermediate the ends. The circular center portion 52 defines an opening 54 which aligns with the blanket chamber port 42 to snugly receive the frustoconical air supply nozzle 38, thereby introducing conditioned air into the pneumatic flow chambers 26 when the fitting plate 46 is opened to its unfolded planar operative configuration as best seen in FIGS. 3 and 4. This open configuration provides full open area flow into the pneumatic flow chambers 26 through the port 42 and provides for easy nozzle 38 insertion into the blanket 10 edge 32.

As seen in FIG. 3, the fitting plate 46 preferably contains explanatory labeling to assist the user in the proper use of the invention and provides for simultaneous labeling of the blanket upper and bottom surfaces without additional labels. The plate first end extension 56 and second end extension 58 are labeled with the words "INLET" to mark the port 42 location into which the conditioned supply air is introduced. On the circular center portion 52, the plate first end 48 to which the upper sheet 12 is attached is identified by the words "THIS SIDE UP", and the plate second end 50 to which the blanket lower surface 22 is attached is identified by the words "THIS SIDE DOWN". Intermediate the plate first end 48 and second end 50 on the center portion 52 is a fold line 60 identified by dashed lines across the fitting plate central portion 52. This fold line is aligned with the blanket edge 32 when the fitting plate 46 is installed on the blanket 10.

Semicircular cuts are made in the blanket upper sheet and lower sheet first ends 34 as seen in FIG. 1, which define the blanket chamber port 42 at which the fitting plate 46 is mounted as in FIG. 1. The plate 46 is aligned with the upper sheet 12 and the laminated assembly 18 and installed in line with the blanket edge 32 forming a hinge-like relationship with the blanket edge 32 as seen in FIG. 5. Because the adhesive is applied only to the plate center portion 52 inner side 62, forming a bond 64, the end extensions are free of the blanket surfaces. By remaining free, the inflated blanket profile and stress to the adhesive bond 64 during inflation are minimized; and the plate first end extension 56 and the plate second end extension 58 may be grasped and separated during nozzle insertion. As shown in FIG. 5, the fitting plate 46 provides concise packaging because it compactly folds along the plate fold line 60 providing a low profile; this configuration has the further advantage of reducing the stress to the interface bond 64 during storage and packaging.

The external conditioned air supply, not shown, can be a separate heating or cooling/dehumidification unit or a unified system and forms no part of the invention. The air supplies are typically transportable low pressure units, similar to a hair dryer construction or the like, having a moderate volume flow rate for which the orifices 20 are sized. The air supply is connected to the blanket by means of the flexible hose 44 as described below.

The pneumatic blanket 10 is typically used to adjust or maintain patient body temperatures through the application of either warming or cooling air for surgical, post operative, hypothermic or hyperthermic patients. In use, pneumatic blanket 10 is fully opened and positioned to cover the body area to be treated; if the whole body is to be covered, then the blanket is positioned lengthwise over the patient with the fitting plate 46 adjacent the patient's feet. Next, the fitting plate 46, which has been folded during storage, is grasped with appropriate fingers behind the extensions 56 and 58 and the thumb or thumbs are positioned at the plate fold line 60 on the outer surface of the plate. By pressing inwardly on the plate fold line 60 while separating extensions 56 and 58 the fitting plate may be opened to a substantially vertical planar configuration as shown in FIG. 4. Next, while maintaining pressure on the fitting plate 46 such that it is in the open, planar configuration the air supply nozzle 38 is inserted into the fitting plate central opening 54 until a snug sealed fit between the plate 46 and the nozzle 38 is obtained as in FIG. 4. Of course, the size of the nozzle 38 and opening 54 are such that the nozzle will tightly wedge into the opening 54 to form an effective seal. Conditioned air may now be supplied to the nozzle which will inflate the blanket and cause the air within the blanket 10 to be exhausted through the blanket orifices 20 in the blanket bottom. By bathing the patient in a constant, gentle flow of air the desired body temperature effect may be achieved without the tissue damage or discomfort often caused by indirect or direct contact with a heat exchanging member.

It is appreciated that various modifications to the inventive concepts may be apparent to those skilled in the art without departing from the spirit and scope of the invention.

We claim:

1. A pneumatic, disposable, temperature control blanket receiving conditioned air through an external air supply connection means, comprising, in combination, an upper thermoplastic air impervious flexible sheet and a lower thermoplastic flexible sheet each having a first end, an opposing second end and edges defining a periphery, said first end lower flexible sheet being adjacent said first end upper flexible sheet, said lower sheet having a lower bottom surface, a heat seal bonding said upper flexible sheet periphery to said lower flexible sheet periphery, a pneumatic flow chamber defined by said sheets, said upper flexible sheet being heat sealed to said lower flexible sheet at a multitude of staking points distributed in a staggered pattern within said sheets' peripheral edges thereby defining redundant multiple air flow paths within said pneumatic flow chamber, an inlet air port defined in said pneumatic flow chamber, an inlet air connection means affixed to said sheets in communication with said inlet air port adapted to receive the inlet air supply connection means to inflate said pneumatic flow chamber, an outer fibrous bottom lamina material bonded to said lower flexible sheet

bottom surface thereby comprising a lower laminated assembly to provide a slide resistant comfortable patient contact surface, an outwardly disposed air flow orifice array defined in said laminated assembly in communication with said pneumatic flow chamber to convey temperature controlled air from said pneumatic flow chamber to the patient, said orifice array comprising a plurality of substantially evenly spaced openings defined in said laminated assembly sized to maintain a predetermined pneumatic flow chamber pressure over a range of predetermined air source volume flow rates.

2. A pneumatic, disposable, temperature control blanket as in claim 1, wherein said inlet air connection means comprises a folding plate affixed to said sheets adjacent said edges thereof defining an opening in communication with said inlet air port adapted to receive the air supply connection means.

3. A pneumatic, disposable, temperature control blanket receiving conditioned air through an external air supply connection means, comprising, in combination, an upper flexible sheet and a lower flexible sheet each having a first end, an opposing second end and edges defining a periphery, said first end lower flexible sheet being adjacent said first end upper flexible sheet, a peripheral bonding means bonding said upper flexible sheet periphery to said lower flexible sheet periphery, a pneumatic flow chamber defined by said sheets having walls, an inlet air port defined in said pneumatic flow chamber, an inlet air connection means affixed to said sheets in communication with said inlet air port adapted to receive the inlet air supply connection means to inflate said pneumatic flow chamber, an outer fibrous bottom lamina material bonded to said lower flexible sheet thereby comprising a laminated assembly to provide a slide resistant comfortable patient contact surface, an outwardly disposed air flow orifice array defined in said laminated assembly in communication with said pneumatic flow chamber to convey temperature controlled air from said pneumatic flow chamber to the patient, said orifice array comprising a plurality of openings sized to maintain pneumatic flow chamber pressure over a range of air source volume flow rates, said inlet connection means comprising an articulating fitting plate having a folded mode and an unfolded inflation mode, an opening defined in said fitting plate in communication with said port adapted to sealingly receive the air supply connection means when said plate is in said unfolded mode, said fitting plate being attached to said upper flexible sheet first end and said lower flexible sheet first end, said inlet air port and fitting plate being located intermediate said upper and lower flexible sheets at said sheet's edges to permit the introduction of supply air in said chamber in the direction of the general plane of the blanket minimizing flow restrictions.

4. A pneumatic, disposable, temperature control blanket for receiving conditioned air through an external air supply nozzle, comprising, in combination, a substantially planar chamber having a flexible upper wall, a flexible lower wall and an edge, a port communicating with said chamber defined in said edge, a folding fitting plate affixed to said upper and lower walls having a central opening in communication with said port, said fitting plate having a fold line in alignment with said chamber edge, said fitting plate central opening adapted to slidably, sealingly receive the air supply nozzle in the blanket plane upon said plate being unfolded, an orifice array defined in said lower chamber wall, said orifices being in communication with said chamber

outwardly disposed to discharge chamber air onto the patient.

5. A pneumatic, disposable, temperature control blanket as in claim 4, wherein said fitting plate comprises an elongated member having a first end defining a first end extension, a second end defining a second end extension and a circular portion intermediate said first and second ends, said circular portion having a central opening defined therein in alignment with said port, adapted to receive the air supply nozzle.

6. A pneumatic, disposable, temperature control blanket as in claim 5, wherein said fitting plate circular portion only is sealingly bonded to said flexible upper wall and said flexible lower wall at said blanket edge

thereby leaving said plate extensions free to move relative said blanket, said circular portion central opening adapted to align and communicate with said port.

7. A pneumatic, disposable, temperature control blanket as in claim 5, wherein said fitting plate is fabricated of a flexible, foldable material with an outer surface adapted to receive indicia thereon.

8. A pneumatic, disposable, temperature control blanket as in claim 7, indicia located on said fitting plate outer surface for explanatory and orientation purposes.

9. A pneumatic, disposable, temperature control blanket as in claim 7, wherein said fitting plate material is cardboard.

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United States Patent [19]

Patent Number: 5,324,320

Augustine et al.

Date of Patent: Jun. 28, 1994

[54] THERMAL BLANKET

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[*] Notice: The portion of the term of this patent subsequent to Feb. 9, 2010 has been disclaimed.

[21] Appl. No.: 703,592

[22] Filed: May 20, 1991

Related U.S. Application Data

[63] Continuation of Ser. No. 227,189, Aug. 2, 1988, abandoned, which is a continuation-in-part of Ser. No. 104,682, Oct. 5, 1987, abandoned.

[51] Int. Cl.: A61F 7/00

[52] U.S. Cl.: 607/107; 165/46; 5/482

[58] Field of Search: 219/12; 34/98, 99; 128/367-369, 373, 400, 402, 403, 379, 380; 62/259.3; 165/46; 5/482, 485

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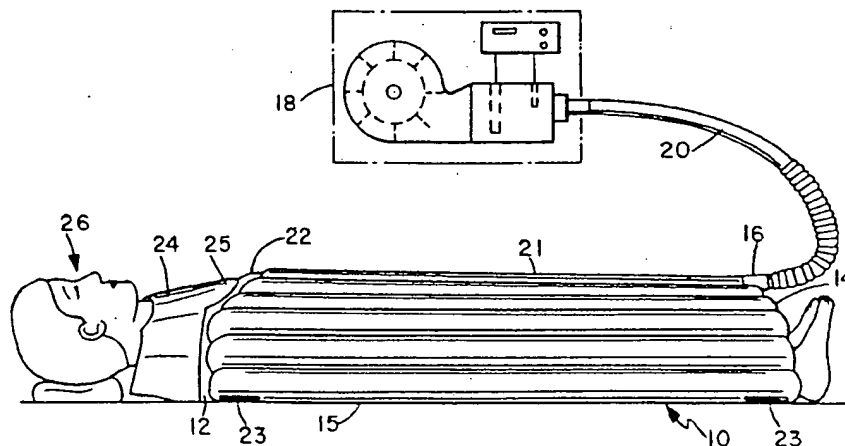
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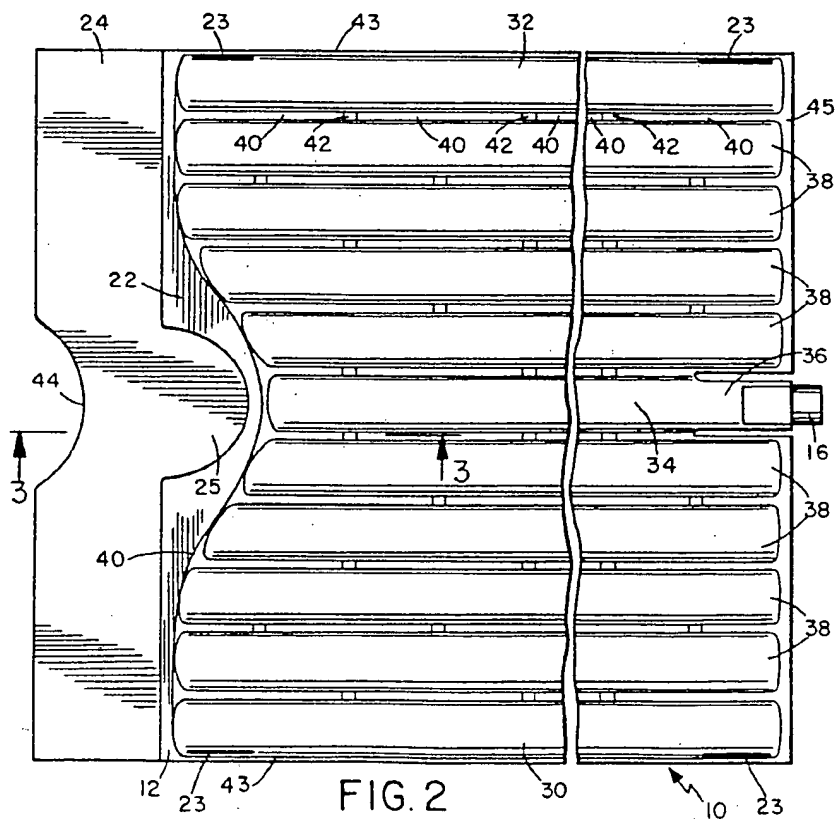
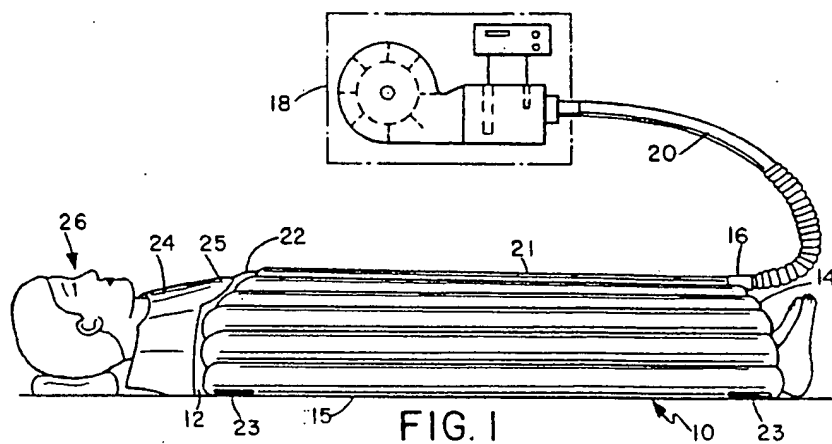
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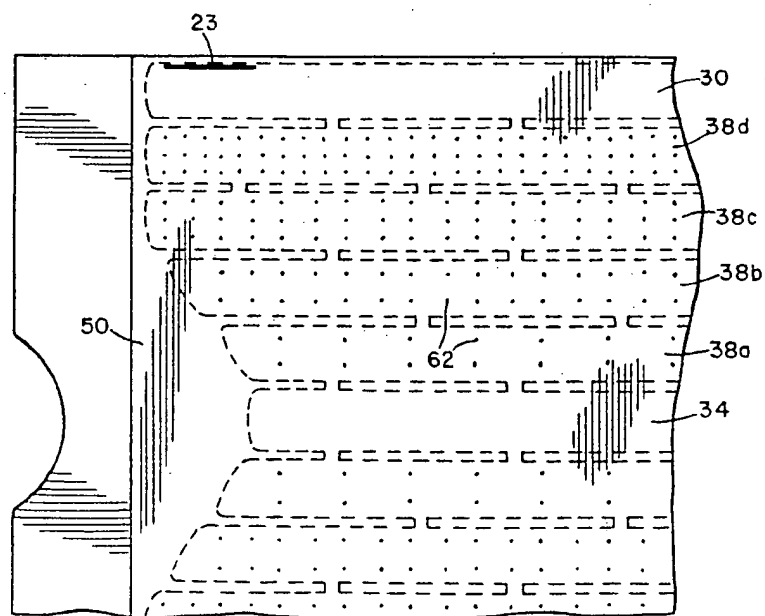
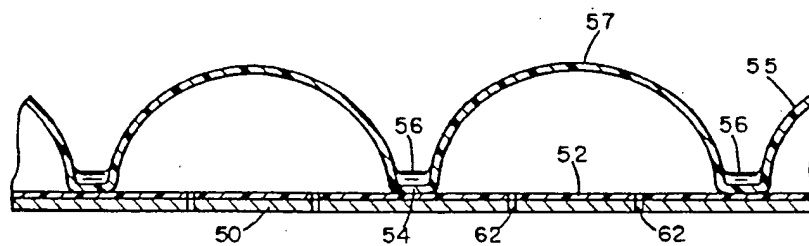
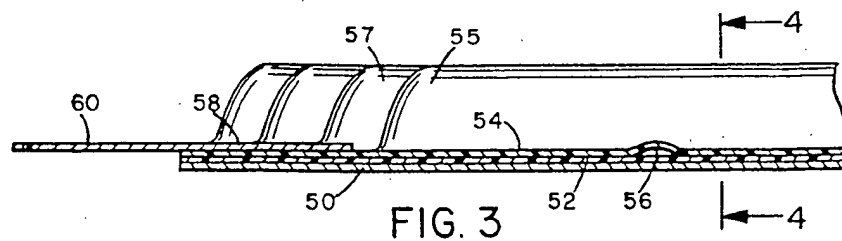
[57] ABSTRACT

A thermal blanket includes an inflatable covering with a head end, a foot end, two edges and an undersurface. The covering is inflated through an inlet at the foot end by a thermally-controlled inflating medium. An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering. Exhaust port openings are provided at the edges of the covering to vent the inflating medium, which enhances circulation of the thermally-controlled medium through the cover. An uninflatable section is provided at the head end, together with an absorbent bib attached to the covering, adjacent the uninflatable section. When inflated, the thermal blanket self-erects and provides a bath of thermally-controlled inflating medium to the interior of the erected structure. The enhanced circulation of the medium through the covers maintains a relatively high average temperature under the blanket and a relatively uniform distribution of temperature in the inflating medium which is exhausted through the apertures into the structure's interior. When the structure covers a patient, the uninflatable section provides a relatively unobstructed view of the patient's face, while the absorbent bib maintains a relatively sanitary environment in the area beneath the patient's head.

24 Claims, 2 Drawing Sheets







THERMAL BLANKET

This is a continuation (FILE WRAPPER) of application Ser. No. 07/227,189 filed Aug. 2, 1988, abandoned, which is a continuation-in-part of application Ser. No. 07/104,682 filed Oct. 5, 1987, abandoned.

BACKGROUND OF THE INVENTION

This invention relates to thermal blankets used in a medical setting to deliver a bath of a thermally-controlled medium to a patient.

The thermal blanket prior art is best expressed in our prior U.S. Pat. No. 4,572,188 entitled "AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE." In our prior patent, a self-erecting, inflatable airflow cover is inflated by the introduction into the cover of a thermally-controlled inflating medium, such as warmed air. When inflated, the cover self-erects about a patient, thereby creating an ambient environment about the patient, the thermal characteristics of which are determined by the temperature of the inflating medium. Holes on the underside of our prior art airflow cover exhaust the thermally-controlled, inflating medium from inside the cover to the interior of the erected structure. Our airflow cover is intended for the treatment of hypothermia, as might occur postoperatively.

Evaluation of our airflow cover by skilled practitioners has resulted in general approbation: the opinion is that the airflow cover efficiently and effectively accomplishes its purpose of giving a thermally-controlled bath. We have realized, however, that, while our prior art airflow cover achieves its objective, certain improvements to it are necessary in order to realize additional clinical objectives and to enjoy further advantages in its use.

SUMMARY OF THE INVENTION

We have improved the clinical usefulness of our self-erecting airflow cover by observing that controlling the contour of its inflatable portion at its head end to define a generally concave non-inflatable portion will permit a care giver to more easily observe a patient's head, face, neck and chest. Further, we have observed that limited venting of the thermally controlled inflating medium from the edges of the cover results in more efficient, more uniform heating within the cover. We have also observed that it is good clinical practice to keep the area of the care site in the vicinity of the patient's head and face as clean as possible.

These three observations have resulted in an improved thermal blanket in which a self-erecting inflatable covering has a head end, a foot end, two edges, and an undersurface. An inflating inlet adjacent said foot end admits a thermally-controlled inflating medium into the covering. An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering into the structure created when the covering self-erects upon inflation. The improvements to this basic structural complement include an uninflatable section at the head end of the covering, exhaust port openings at the edges of the covering, an absorbent bib attached to the covering at the head end adjacent the uninflatable section, and structural features that make the covering simple and economical to produce.

With these improvements, the thermal blanket, when inflated and erected over a patient, delivers the thermally-controlled inflating medium into the interior of the structure covering the patient, thereby thermally bathing the patient. The first improvement permits full viewing of the head and face of the patient from almost any aspect around the thermal blanket. The exhaust port openings increase the rate of circulation of the inflating medium within the blanket, thereby increasing the temperature within the structure and making the temperature distribution more uniform. The absorbent bib soaks up and retains liquids which might otherwise spread over the care site in the area of a patient's head. Such liquids can include the patient's own perspiration, blood, vomit, saliva, or liquids which are administered to the patient. The absorbent bib also acts to some extent to seal the head end of the inflated structure.

From another aspect, the invention is a thermal blanket for covering and bathing a person in a thermally-controlled medium. The thermal blanket includes a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures opening between the first and second surface of the base sheet. An overlying material sheet is attached to the first surface of the base sheet by a plurality of discontinuous seams which form the material sheet into a plurality of substantially parallel, inflatable chambers. A continuous seam is provided between the material sheet and the base sheet at the head end to form a non-inflatable viewing recess at the head end. Exhaust port openings are provided through the material sheet to vent the medium from the chambers away from the base sheet. An absorbent bib is attached to the head end in the vicinity of the viewing recess.

Therefore the invention accomplishes the important objective of providing a self-erecting, inflatable thermal blanket that permits a relatively unobstructed view of a patient's head and face when in use.

Another objective is the efficient and uniform heating of the interior of the structure created when the blanket is inflated with a heat inflating medium.

A signal advantage of the invention is the provision of such a blanket with a means for maintaining the cleanliness of the care site in the vicinity of the patient's head and face.

The advantageous simplified structure of the thermal blanket make its production straightforward and economical.

These and other important objectives and advantages will become evident when the detailed description of the invention is read with reference to the below-summarized drawings, in which:

FIG. 1 is a side elevation view of the thermal blanket in use, with associated thermal apparatus indicated schematically;

FIG. 2 is an enlarged top plan view of the thermal blanket opened flat;

FIG. 3 is an enlarged sectional view taken along 3-3 of FIG. 2;

FIG. 4 is a further enlarged sectional view taken along line 4-4 of FIG. 3; and

FIG. 5 is a partial underside view of the thermal blanket.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

When used herein, the term "thermal blanket" is intended to be interchangeable with, but not necessarily

limited by, the term "airflow cover" used in our U.S. Pat. No. 4,572,188, which is incorporated herein in its entirety by reference. In this description, the term "thermal blanket" is meant to invoke a self-erecting, inflatable structure for delivering a thermally-controlled inflating medium to the interior of the structure created when the thermal blanket is inflated. The purpose of the thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within the erected structure.

Our invention is illustrated as we intend for it to be used in FIG. 1. In FIG. 1, a self-erecting, inflatable thermal blanket 10 has a head end 12, a foot end 14 and two lateral edges, one indicated by 15. An inflation inlet cuff 16 is connected to a heater/blower assembly 18 which provides a stream of heated air through a connecting hose 20. When the heater/blower 18 is operated, the stream of heated air flows through the inflating hose 20 into the thermal blanket 10 through the inflation cuff 16. When the blanket is inflated, it erects itself into a Quonset hut-like structure with a quilted upper surface 21. As described below, a pattern of apertures on the undersurface of the blanket (not shown in FIG. 1) delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

The contour of the inflatable portion of the thermal blanket 10 is varied at the head end 12 of the blanket to provide a non-inflated blanket recess 22 in the quilted upper surface 21, which remains smooth and flat when the blanket is inflated and erected. Circulation of the heated air is accelerated through the thermal blanket by exhaust port openings in the upper surface, adjacent the lateral edges of the blanket. Two exhaust port openings are indicated by reference numeral 23. Further, a bib 24 made of an absorbent material is attached to the head end 12 of the thermal blanket in the vicinity of the non-inflated recess 22. In fact, as shown in FIG. 1 the bib 24 includes a semi-circular tab 25 that extends into the recess 22.

As illustrated in FIG. 1, the thermal blanket of the invention is inflated, erects itself into a bathing structure, and bathes a patient 26 with the thermally-controlled air used to inflate the structure. While the patient is being thermally bathed, the uninflated recess 22 permits observation of the patient's head, face, neck, and chest from almost any location with respect to the thermal blanket 10. Thus, if the patient is placed on a gurney or a bed, the head of which is against a wall, a care giver such as a nurse, intern, resident, or doctor, can keep the patient's face under observation from the foot end 14 of the thermal blanket 10. Respiration can be detected by the rise and fall of the bib and uninflated area, which rest directly on the patient's chest. Moreover, the bib 24 will provide an absorbent sink for stray, unconfined liquids in the area of the patient's head or at the head end 12 of the thermal blanket 10.

FIG. 2 is a plan view of the thermal blanket 10 opened flat to show details of its structure. FIG. 2 illustrates the upper surface of the thermal blanket, that is the side that is visible in FIG. 1. As seen, the upper surface consists of a parallel array of elongated tubes of which 30 and 32 are the lateralmost tubes, 34 is the center tube, and the tubes 38 are arrayed between one of the lateralmost tubes and the center tube. Each tube is separated from an adjacent tube by a discontinuous seam, one of which is indicated by 40. The seam 40 separates the tube 32 and its nearest adjacent neighbor 38. The discontinuous seam 40 is interrupted by pas-

sageways 42 communicating between the tubes. An interrupted seam separates every tube from one adjacent neighboring tube. The seams permit the thermal blanket, when inflated, to assume a tubular structure on the upper surface, while the ports 42 permit full circulation of the inflating medium throughout the array of tubes. The foot-end seam 45 is continuous. The tubes are inflated through the center tube 34 which transitions to a port 36, through which the inflation cuff 16 is inserted. The edge seams 43 are discontinuous only at the exhaust port opening locations 23. A seal can be made between the inflation port 36 and the inflation cuff 16 by any conventional means, for example, an O-ring, or even tape. When the inflating medium is introduced into the center tube 34, it flows laterally from the center tube into all of the other tubes through the ports 42. Near the head end 12, a continuous seam 40 defines the forward end of all of the tubes, with the seam assuming a bell-curve shape. On the head end side of the seam 40, the thermal blanket 10 is uninflatable. The bell-shaped seam 40 thus defines the uninflatable area 22 at the head end of the thermal blanket 10, which is essentially coplanar with, or substantially parallel to, the underside of the blanket. As shown in FIG. 1, by virtue of its structural integration with the rest of the thermal blanket 10, the non-inflated recess extends over the upper chest of the patient 26 when the blanket is inflated. However, since the recess 22 is uninflated, it provides a wide-angled viewing gap in the inflated contour of the upper surface 21. The gap is filled by continuation of the underside of the blanket. It is also noted that the pattern of inflatable tubes can be replaced by other suitable patterns of communicating, inflatable chambers. The tubes are preferred since they impart strength and shape to the erected bathing structure; other inflatable structures are contemplated, however.

The absorbent bib has an indent 43 cut into its outside edge, which permits the blanket to be drawn up to the chin of a patient and which provides absorbercy laterally up the neck of the patient. The absorbent bib can consist of any absorbent material such as a single- or multi-ply tissue paper which is used to make paper towels.

Construction details of the thermal blanket 10 are illustrated in FIGS. 3 and 4. The thermal blanket 10 is assembled from a base sheet consisting of an underside layer 50 formed from flexible material capable of bonding to a layer 52 of heat-sealable plastic. For the layers 50 and 52, we have used a stratum of absorbent tissue paper prelaminated with a layer of heat-sealable plastic. Material of such construction is commercially available in production rolls and is used to make painters' drop cloths. The upper side of the thermal blanket consists of a sheet of plastic bonded to the plastic layer 52 by an interruptible heat-sealing process to form the interrupted seams, one of which is indicated by 54, and the inflatable tubes, one indicated by 55. As can be seen in FIG. 3, the interruption of the seam 54 forms a passageway 56 between adjacent tubes 55 and 57.

The absorbent bib and tab are shown in FIG. 3 as a single material layer 60/58. Alternatively, they may be formed from separate material sheets cut to the outlines illustrated in FIG. 2. The absorbent material forming the bib and tab can be bonded to the upper plastic layer by heat process or by gluing.

The inventors also contemplate deletion of the bib and tab. In this instance, the thermal blanket would still have the viewing recess, which would be defined by the

continuous seam at the head end, and which would be filled with the forward portion of the base sheet.

Circulation of heated air through the blanket is enhanced by the exhaust port openings 23, which open through the upper plastic sheet 22, which is heat sealed to the base of the blanket. The openings 23 vent the heated inflating air out of the outermost tubes 30 and 32, away from the underside of the blanket. Because air can circulate to, and through, the blanket edges, the inflating air in the outermost tubes is hotter than if the openings were absent. This results in hotter air being delivered through the underside apertures toward the edge of the blanket. We have measured the temperature distribution within the thermal blanket for inflating air which is heated to a medium temperature range and for inflating air which is heated to a high temperature range. The results are provided in Table I for a blanket consisting of 13 tubes. Measurements of the temperature of air exhausted through underside apertures were made on the underside of each tube on one side of the blanket. The tubes are numbered 1-6, with 1 being the tube adjacent to the center tube, and tube 6 being the outermost tube adjacent on lateral edge of the blanket. Test apertures were made in the bottom of tube 6 only for the purposes of this test. As is evident, the distribution of temperature within the erected thermal blanket is more uniform when the exhaust port openings are provided. Further, provision of the exhaust ports also increases the average temperature within the erected structure of the blanket. Clearly, the provision of exhaust port openings at the lateral edges of the blanket delivers results which one would not expect when considering the operation of our thermal blanket with no exhaust port openings.

In our preferred embodiment, the exhaust port openings are slits in the edge seams of our blanket. These slits vary in length from 1 1/4 to 2 inches. Each edge seam is discontinuous approximately at each corner of the blanket so that inflating air is vented away from the underside of the erected blanket. This keeps the relatively "colder" air at the blanket edges from mixing with the relatively "hotter" air exhausted into the structure through the underside apertures. The result is a "flatter" temperature profile of air within the blanket than without the vents, which raises the average temperature within the erected structure and makes the temperature distribution in the structure more uniform. Resultantly, the clinical effect of the blanket is enhanced. Heating is better controlled, and more uniform, with greater comfort to the patient.

TABLE I

TUBE NO.	MEDIUM TEMPERATURE RANGE		HIGH TEMPERATURE RANGE	
	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS
center (inlet) tube	113.3° F.	114.1° F.	121.3° F.	121.3° F.
Tube #1	109.9°	112.3°	117.3°	117.7°
Tube #2	105.3°	109.8°	113.4°	115.0°
Tube #3	103.2°	107.1°	111.0°	113.3°
Tube #4	99.9°	104.3°	101.4°	108.6°
Tube #5	97.2°	100.0°	95.7°	104.4°
Tube #6 (outermost)	85.2°	93.8°	89.6°	99.4°
Average	103.8°	106.7°	108.4°	112.5°

TABLE I-continued

TUBE NO.	MEDIUM TEMPERATURE RANGE		HIGH TEMPERATURE RANGE	
	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS
temp. under cover				

The thermal blanket of the invention is enabled to bathe a patient in the thermally-controlled inflating medium introduced into the upper side tubes by means of a plurality of apertures, 62 shown in FIGS. 4 and 5. The apertures extend through the underside of the blanket, which includes the layers 50 and 52. The apertures 62 are made in the footprints of the tubes of the blanket upper side according to a pattern which has been determined to deliver a very uniform thermal bath. In this regard, no apertures are provided through the underside into the lateralmost tubes 30 and 32, or into the center tube 34. In addition, the apertures 62 are provided through the underside to the apertured tubes in a density which varies inversely with the proximity of the tube to the center tube 34. Thus, the hole density increases from the tube 38a through the tube 38d. Even with the exhaust port openings, the temperature of the inflating medium exhibits a drop from the center to the lateralmost tubes. The varying density of the apertures 62 tends to reduce this gradient further by forcing hotter air to the edges of the blanket. Thus, the thermal bath delivered to the patient is of a generally uniform temperature. The aperture density variation also equalizes the flow of inflating medium out of the apertures. As will be evident, the inflating pressure will be greatest at the center tube 34 and will tend to diminish toward the lateral edges of the thermal blanket. Therefore, fewer apertures are required for the tubes near the center tube 34 to deliver the same amount of air as the relatively greater number of apertures in the tubes at a greater distance from the center tube 34.

The apertures comprise openings which can be of any appropriate shape. For example, we have produced blankets with elongated apertures, approximately 1/4 inch in length.

Many modifications and variations of our invention will be evident to those skilled in the art. It is understood that such variations may depart from specific teachings of this description without departing from the essence of the invention, which is expressed in the following claims.

We claim:

1. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled medium, the improvement comprising:
 - a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;
 - an overlaying plastic sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said plastic sheet into a plurality of communicating inflatable chambers, said apertures opening through said base sheet into said chambers;
 - a continuous seam between said plastic sheet and said base sheet at said head end which forms a non-inflatable viewing recess; and

an exhaust vent in said overlaying plastic sheet and adjacent a first edge, opening from a first inflatable chamber adjacent said first edge, for venting an inflating medium away from said base sheet.

2. The self erecting, inflatable thermal blanket of claim 1 including an absorbent bid attached to the head end of said base sheet.

3. In a self-erecting, inflatable, convective thermal blanket for covering and bathing a person with a thermally-controlled, inflating medium wherein the improvement comprises:

- a flexible base sheet having two ends and two edges;
- a flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form a plurality of communicating, inflatable chambers between said flexible base sheet and said flexible material sheet;
- a means for admitting an inflating medium into said chambers;
- said flexible base sheet including means for permitting passage of said inflating medium from said chambers through said flexible base sheet; and
- a vent means in said flexible material sheet adjacent a first edge of said flexible base sheet for circulating said inflating medium through said inflatable chambers by exhausting said inflating medium from a first inflatable chamber adjacent said first edge.

4. The thermal blanket of claim 3, wherein said flexible base sheet includes an undersheet of flexible, fibrous material and a sheet of plastic material coextensive with, and attached to, said undersheet.

5. The thermal blanket of claim 4, wherein said discontinuous seams are substantially elongate seals, formed between said flexible material sheet and said flexible base sheet, which form said inflatable chambers into a plurality of mutually parallel, communicating tubular chambers extending between said two ends.

6. An inflatable, convective thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, comprising:

- a flexible base sheet having ahead end, a foot end, two edges, and a plurality of apertures;
- an plastic sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said plastic sheet into a plurality of communicating, inflatable chambers, said apertures opening through base sheet into said chambers; and
- an exhaust vent opening through said plastic sheet into a first inflatable chamber adjacent said first edge, for circulating an inflating medium through said inflatable chambers by venting said inflating medium from said first inflatable chamber.

7. In a self-erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, the improvement comprising:

- a flexible base sheet having a head end, a foot end, two edges, a plurality of apertures;
- an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;
- a continuous seam between said overlaying material sheet and said base sheet near said head end which closed ends of said inflatable chambers; and
- a non-inflatable section of said thermal blanket extending substantially between said continuous seam

and said head end and including an end portion of said flexible base sheet.

8. The improvement of claim 7 wherein said base sheet includes an undersheet of flexible fibrous material and a sheet of plastic material co-extensive with, and attached to, said undersheet.

9. The improvement of claim 7 wherein said base sheet includes a multi-layered structure in which the bottom-most layer is a paper sheet bonded to an upper sheet of plastic material.

10. The improvement of claim 8 wherein said discontinuous seams are substantially elongate seals formed between said overlaying material sheet and said sheet of plastic material, and said continuous seam is an elongate seal which extend between said edges substantially transversely to said elongate seals.

11. The improvement of claim 8 wherein one of said discontinuous seams includes a sequence of co-linear seals extending substantially from said foot end to said continuous seam.

12. The improvement of claim 11 wherein said plurality of discontinuous seams form said overlaying material sheet into a plurality of mutually parallel, communicating tubular chambers.

13. The improvement of claim 7 including exhaust port openings through said overlaying material sheet for circulating said inflating medium within said thermal blanket toward said two edges.

14. The improvement of claim 7 including a patterned array of apertures opening through said underside into said chambers, said patterned array comprising a density pattern in which the density of said apertures increases toward one of said edges.

15. The improvement of claim 12 including a patterned array of apertures, said apertures opening through said base sheet into said chambers, said patterned array comprising a density pattern in which the density of said apertures increases toward one of said edges.

16. The improvement of claim 15 wherein one of said tubular chambers is centrally positioned in said parallel tubular chambers and said density increases from said central position chamber toward one of said edges.

17. The improvement of claim 16 wherein no apertures open through said base sheet into said centrally positioned tubular chamber.

18. The improvement of claim 17 wherein no apertures open through said base sheet into a tubular chamber adjacent one of said edges.

19. An inflatable thermal blanket for convectively controlling the temperature of a human body, comprising:

- a self-erecting, inflatable covering with a head end, a foot end, two edges, and an undersurface;
- an inflating inlet for admitting a thermally controlled, inflating medium into said covering;
- an array of apertures in said undersurface for exhausting a thermally controlled inflating medium from said covering to said undersurface;
- means in said inflatable covering for equalizing the temperature of the thermally controlled inflating medium in said inflatable covering by circulating said inflating medium toward said two edges; and
- an inflatable extension in said inflatable covering at said end;

wherein said array of apertures is in a pattern which increases the density of said apertures from a cen-

tral location on said undersurface in a direction toward a first one of said two edges.

20. The thermal blanket to claim 19 wherein the pattern increases the density of said apertures from said central location in a direction toward the second of said two edges.

21. A convective thermal blanket for being inflatably erected to enclose and bathe a person in a thermally-controlled inflating medium, comprising:

flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures, the base sheet including a first layer of non-plastic material and a second layer of plastic material attached to said first layer;

an overlaying plastic sheet attached to said second layer of said base sheet by a plurality of discontinuous means which form said plastic sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers;

a continuous seal transverse to and closing ends of said inflatable chambers, the continuous seal being between said plastic sheet and said second layer of said base sheet near said head end; and

an uninflatable viewing portion extending between said head end and said continuous seal, said viewing portion including respective extensions of said base sheet and said plastic sheet.

22. A self erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, comprising:

a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which form said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers; and

means in an inflatable chamber and responsive to a thermally-controlled inflating medium for equalizing the temperature of said thermally-controlled inflating medium within said chambers;

wherein said means includes vent ports in said inflatable chamber, said vent ports through said overlaying flexible material sheet.

23. A self erecting, inflatable thermal blanket for covering and bathing a person in a thermally-controlled inflating medium, comprising:

a flexible base sheet having two ends, two edges, and a plurality of apertures;

an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams which extend substantially between said two ends and at least two continuous seams which extend substantially between said edges, said discontinuous and continuous seams forming said overlaying material sheet into a plurality of communicating, inflatable chambers, said apertures opening through said base sheet into said chambers; and

means in a first inflatable chamber for equalizing the temperatures of said thermally-controlled inflating medium by circulating said thermally-controlled inflating medium within said chambers to said edges;

wherein said means includes an opening in said overlaying plastic sheet into said first chamber.

24. An inflatable, self-erecting thermal blanket for bathing a person in an inflating medium, comprising:

a flexible undersheet;

the flexible undersheet including a layer of a first flexible material;

the flexible undersheet including a layer of a second flexible material bonded to the layer of first flexible material;

an overlaying, flexible material sheet attached to the layer of second flexible material by a plurality of discontinuous seams which form the overlaying material sheet into a plurality of communicating, inflatable chambers;

a plurality of apertures opening through the layer of first flexible material and the layer of second flexible material of the undersheet into the chambers;

means for admitting a thermally-controlled, inflating medium into the chambers; and

a vent port opening through the overlaying material sheet into one of the chambers for circulating a thermally-controlled, inflating medium toward one of said edges.

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Zeichen/Ref/Réf BEC/0545-03EPO	Anmeldung Nr./Application No./Demande n°/Patent Nr./Patent No./Brevet n° 88309191.0- /
Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire Augustine, Scott D., et al	

COMMUNICATION

The European Patent Office herewith transmits

- ☒ the European search report
- ☐ the declaration under Rule 45 of the European Patent Convention
- ☐ the partial European search report under Rule 45 of the European Patent Convention
- ☐ the supplementary European search report concerning the international application number

relating to the above-identified European patent application; copies of the documents cited in the search report are enclosed.

The Search Division approved the following items, as submitted by the applicant:

- ☐ Abstract ☒ Title ☒ Figure
- ☒ The abstract was modified by the Search Division and the definitive text is attached to the present communication.

- ☐ The following figure will be published with the abstract, since the Search Division considers that it better characterizes the invention than the one indicated by the applicant.

Figure:

- ☒ Additional copy(ies) of the documents cited in the European search report.





DOCUMENTS CONSIDERED TO BE RELEVANT			EP 88309191.0
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
D,A	US - A - 4 572 188 (AUGUSTINE) * Abstract; column 2, line 64 - column 3, line 50; fig. 1,2 *	1,6,7,12	A 61 F 7/00 A 61 F 7/08
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A	DE - A1 - 3 308 553 (SMIDT) * Abstract; fig. 1,2,3 *	1	
	--		
A	US - A - 3 714 947 (HARDY) * Abstract; fig. 1 *	1	

The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 23-12-1988	Examiner TSILIDIS
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone			T : theory or principle underlying the invention
Y : particularly relevant if combined with another document of the same category			E : earlier patent document, but published on, or after the filing date
A : technological background			D : document cited in the application
O : non-written disclosure			L : document cited for other reasons
			A : member of the same patent family, corresponding

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 88 30 9191

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office (EPO) file on 24/01/89. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4572188	25-02-86	None	
DE-A- 3308553	20-09-84	US-A- 4718429	12-01-88
US-A- 3714947	06-02-73	None	

①9 BUNDESREPUBLIK
DEUTSCHLAND



DEUTSCHES
PATENTAMT

①2 **ffenlegungsschr t**
①1 **DE 3308553 A1**

biol.
⑤1 Int. Cl. 3:
A61 F 7/00

⑦1 Aktenzeichen: P 33 08 553.6
⑦2 Anmeldetag: 10. 3. 83
④3 Offenlegungstag: 20. 9. 84

DE 3308553 A1

⑦1 Anmelder:
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⑦2 Erfinder:
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Prüfungsantrag gem. § 44 PatG ist gestellt

⑤4 **Kühl-Auflage für den menschlichen Körper**

Die flächige Kühl-Auflage weist Durchströmungskanäle auf, die mit von einer Kühlmittelquelle zugeführtem Kühlmittel mit gegenüber der Körpertemperatur niedrigerer Temperatur durchströmbar ist.

Die Auflage kann die Form eines die zu behandelnden Körperteile umschließenden Kleidungsstücks oder die Form einer Matte haben, auf welcher die zu behandelnde Person ruht bzw. mit welcher sie bedeckt wird.

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3. Auflage nach Anspruch 2, dadurch gekennzeichnet, daß die Auflage (10) die Form eines die zu kühlenden Körperpartien bedeckenden Kleidungsstücks hat.
4. Auflage nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Auflage die Form einer Matte (14) hat, die auf die Matratze eines Bettes auflegbar bzw. in eine Bettdecke einziehbar ist.
5. Auflage nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Durchströmungskanäle (12; 16) zwischen zwei thermoplastischen Kunststoffolien (26; 28) gebildet sind, die entlang der Begrenzungen der Durchströmungskanäle (12; 16) miteinander verschweißt sind.
6. Auflage nach Anspruch 5, dadurch gekennzeichnet, daß auf die Außenfläche der der zu kühlenden Körperpartie zugewandten Kunststoffolie (26) eine dünne Metallfolie (32), vorzugsweise eine Aluminiumfolie, aufkaschiert ist.
7. Auflage nach Anspruch 5 oder 6, dadurch gekennzeichnet, daß auf der Außenfläche der der zu kühlenden Körperpartie abgewandten Kunststoffolie (28) eine Schicht aus wärmeisolierendem elastischem Material (34) aufgebracht ist.
8. Auflage nach Anspruch 7, dadurch gekennzeichnet, daß die wärmeisolierende Schicht (34) eine Schicht aus Schaumkunststoff oder Schaumgummi ist.

15. Auflage nach Anspruch 13, dadurch gekennzeichnet, daß die Kälteanlage eine nach dem Absorptionsverfahren arbeitende Kälteanlage ist.
16. Auflage nach einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, daß in der Zuführ- (18) und/oder der Abführleitung (24) der Fühler je eines Temperatur Meß- oder Registrierinstruments vorgesehen ist.
17. Auflage nach einem der Ansprüche 1 bis 16, dadurch gekennzeichnet, daß in der Zuführ- (18) und/oder Abführleitung (24) der Fühler je eines die Durchflußmenge des Kühlmittels steuernden einstellbaren Thermostaten vorgesehen ist.
18. Auflage nach einem der Ansprüche 1 bis 17, dadurch gekennzeichnet, daß zusätzlich zu dem System der Kühlmittel-Durchströmungskanäle (12; 16) ein gegenüber diesem getrenntes System von Durchströmungskanälen mit gesonderter Zuführ- und Abführleitung für ein zweites Strömungsmittel mit von der Temperatur des Kühlmittels abweichender Temperatur vorgesehen ist.

Abfallwärme produzieren und abgeben und somit auch insgesamt weniger Energie verbrauchen. Da die Erzeugung von Wärme aber auch der Regelung und Aufrechterhaltung der Körpertemperatur dient, kann man sie durch Wärmeentzug intensivieren. Der Körper produziert Wärme auf zwei Wegen, nämlich einerseits durch Herabsetzung des Wirkungsgrades bestimmter chemischer Prozesse, wobei mehr Abfallwärme produziert wird, und zum anderen durch Muskelzittern, d.h. die periodische Kontraktion und Entspannung von Muskeln, wobei die hierfür erforderlichen energieliefernden chemischen Reaktionen ebenfalls Wärme erzeugen.

Ausgehend von der Erkenntnis, daß sich durch Wärmeentzug eine oder beide der vorstehend geschilderten Prozesse anregen lassen, und der Körper somit gezwungen wird, von der aufgenommenen und hauptsächlich in Form von Fettdepots gespeicherten Energie einen größeren Anteil in Wärme umzuwandeln, wird die gestellte Aufgabe erfindungsgemäß gelöst durch die Verwendung einer der oben beschriebenen Kühlkleidung funktionell ähnlichen, zum Entzug von Wärmeenergie aus oberflächennahen Partien des menschlichen Körpers mittels Durchströmung mit einem Kühlmittel geeigneten Auflage als Mittel zur Körpergewichtsreduktion.

Die zweckmäßig in der Größe der zu kühlenden Körperpartie entsprechend bemessene Auflage ist dabei vorzugsweise aus einem sich der Körperpartie anschmiegenden Material hergestellt, wobei sie in an sich bekannter Weise die Form eines die zu kühlenden Körperpartien bedeckenden Kleidungsstücks haben kann, welches von der zu behandelnden Person angelegt und während bestimmter Behandlungsdauern getragen wird.

vermag. Als Kältespeicher können beispielsweise zuvor in einer tiefgekühlten Atmosphäre, beispielsweise einer Kühltruhe, unterkühlte sogenannte "Kühlakkus" Verwendung finden.

Andererseits kann die Rückkühlvorrichtung auch ein an eine gesonderte Kühlvorrichtung angeschlossener Wärmetauscher sein, in welchem dem Kühlmittel die von den gekühlten Körperpartien aufgenommene Wärmeenergie entzogen wird. Im einfachsten Fall kann der Wärmetauscher in einem mit Wasser aus dem Leitungsnetz durchströmbaren Behälter angeordnet sein, wobei der Zu- und Abfluß des Wassers in diesen Behälter in Abhängigkeit von der Erwärmung der Wassertemperatur steuerbar ist.

Um die Durchströmung der Auflage mit dem Kühlmittel sicherzustellen, empfiehlt es sich dabei, in die Zuführleitung eine motorisch antreibbare Pumpe ein- bzw. der Zuführleitung vorzuschalten.

Alternativ kann die Auflage auch als Verdampfer in einen geschlossenen Kühlkreislauf einer Kälteanlage eingeschaltet sein, wobei die Kälteanlage entweder nach dem Kompressionsverfahren oder nach dem Absorptionsverfahren arbeiten kann.

In der Zuführ- und/oder der Abführleitung kann der Fühler je eines Temperatur-Meß- oder Registrierinstruments vorgesehen sein. Aus einem Vergleich der Eintritts- und der Austrittstemperatur in die bzw. aus der Auflage läßt sich dann unter Berücksichtigung der Menge und spezifischen Wärme des über die ebenfalls registrierbare Einschaltdauer und Förderleistung der das Kühlmittel

Die in Figur 1 gezeigte, als von einer zu behandelnden Person anlegbare Weste 10 ausgebildete erfindungsgemäße Auflage möge aus zwei Lagen einer flüssigkeits- und gasdichten thermoplastischen Kunststoffolie hergestellt sein, wobei die in der Zeichnung nur schematisch gestrichelt angedeuteten Durchströmungskanäle 12 durch Verschweißen der beiden Folienlagen entlang der Begrenzungen der Durchströmungskanäle entsprechend dem vorgegebenen Kanalmuster gebildet sein können. Wenn das Kanalmuster in einer der Folienlagen voreingeprägt ist, kann die zweite Folienlage - und zwar zweckmäßig die später dem Körper der zu behandelnden Person zugewandte Lage - in ebenflächiger Form mit der mit dem geprägten Kanalmuster versehenen Folienlage verschweißt (oder verklebt) werden. Über wenigstens eine (nicht gezeigte) Zuführ- und eine Abführleitung ist ein flüssiges oder dampf- oder gasförmiges Strömungsmedium als Kühlmittel in das System der Durchströmungskanäle 12 einspeisbar und wieder aus ihm abführbar, wobei die Leitungen so am Kanalmuster angeschlossen sind, daß eine möglichst gleichmäßige und vollständige Durchströmung sämtlicher Kanäle erfolgt. So kann die Zuführleitung beispielsweise im Bereich des unteren Randes und die Abführleitung im Bereich des Halsausschnittes jeweils auf der Rückseite der Weste an das Kanalsystem angeschlossen werden. Das Kühlmittel kann dann über die Leitungen von einem auf dem Rücken des Benutzers aufgeschnallten oder - über Verbindungsschläuche - auch von einem gesondert aufgestellten, d.h. weggebauten, Kühlmittelvorrat bzw. Kühltagegregat zu- und abgeführt werden. Die Umwälzung des Kühlmittels könnte - bei flüssigen Kühlmitteln - im einfachsten Fall aufgrund des sogenannten "Thermosyphoneffekt" erfolgen. Eine genauere Steuerung der Durchströmungsmenge in Abhängigkeit von der über den Kühlmittelkreislauf abzuführende Körperwärme ist jedoch durch eine

ist, daß die Durchströmungskanäle 16 durch Vorformung oder Einprägung von kanalartigen Vertiefungen 30 in die körperabgewandte Folie 28 gebildet werden. Durch die ebenflächig auf die Folie 28 aufgelegte und entlang der Ränder der Vertiefung verschweißte körpernähere Folie 26 entstehen dann die geschlossenen Durchströmungskanäle 16. Auf die Außenfläche der Folie 26 ist eine dünne Aluminiumfolie 32 aufkaschiert, welche die flächige Wärmeaufnahme von den anliegenden Körperpartien verbessert.

Auf der Außenseite der körperabgewandten Folie 28 ist dagegen eine dickere, wärmeisolierende Schicht 34 aus aufgeschäumtem Kunststoff, beispielsweise eine Polyurethan-Schaumschicht aufgebracht, welche neben der thermischen Isolierung der Durchgangskanäle 16 gegen Wärmeaufnahme aus der Umgebung auch einen Schutz gegen mechanische Druckbeanspruchungen der Durchgangskanäle bietet.

Im Falle der Ausbildung der Auflage als Kleidungsstück entsprechend der in Fig. 1 gezeigten Weste, kann diese wärmeisolierende Schicht 34 natürlich auch als von der Weste 10 getrennte, gesonderte Isolierweste ausgebildet werden.

Die in Fig. 4 gezeigte, ebenfalls mattenförmige Auflage 14 entspricht der vorstehend in Verbindung mit den Figuren 2 und 3 beschriebenen Auflage 14 weitgehend mit der Ausnahme, daß die Durchströmungskanäle 16 nicht parallel und geradlinig von der einen zur anderen Schmalseite der Auflage, sondern in einem hiervon abweichenden, symmetrisch zur quer zur Mattenlängserstreckung verlaufenden Mittellinie der Auflage 14 ausgebildeten schleifenförmigen Kanalmuster ausgebildet sind, wobei die

Person subjektiv als unangenehm empfundene Gefühl der Unterkühlung der behandelten Körperpartien durch Aufwärmung nach der Behandlung schnell beseitigt werden.

Als Kühlmittel können Flüssigkeiten, z.B. Wasser oder Salzlösungen (Sole) Verwendung finden, die nach der Durchströmung der Auflage in geeigneter Weise rückgekühlt werden. Andererseits können auch die heute in Kälteanlagen in großem Umfang verwendeten und in Abhängigkeit von den Druck- und Temperaturbedingungen teilweise flüssigen und teilweise dampfförmigen Fluor-Kohlenwasserstoff-Kühlmittel direkt zur Durchströmung der Auflage verwendet werden, die dann funktionell dem Verdampfer einer Kühlanlage entspricht.

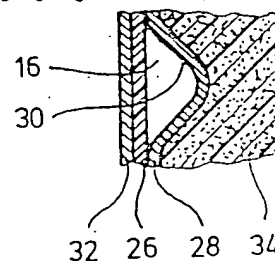
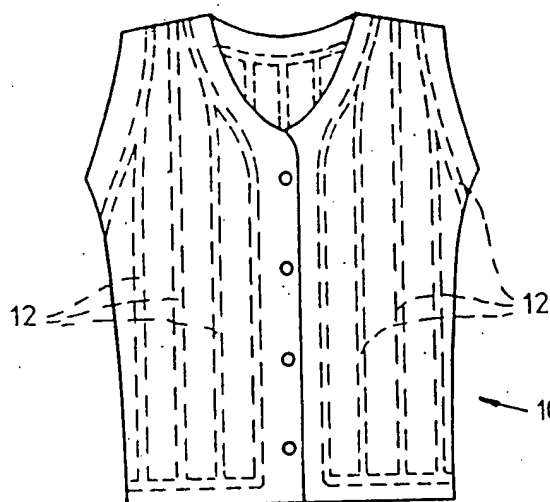


Fig. 3

Fig. 1

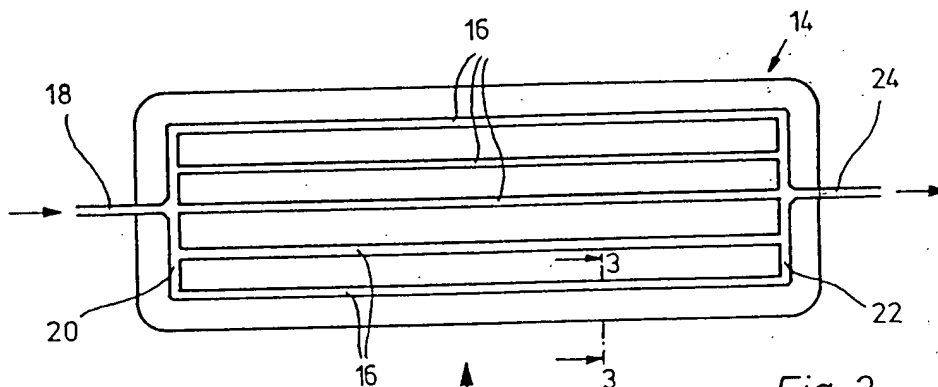


Fig. 2

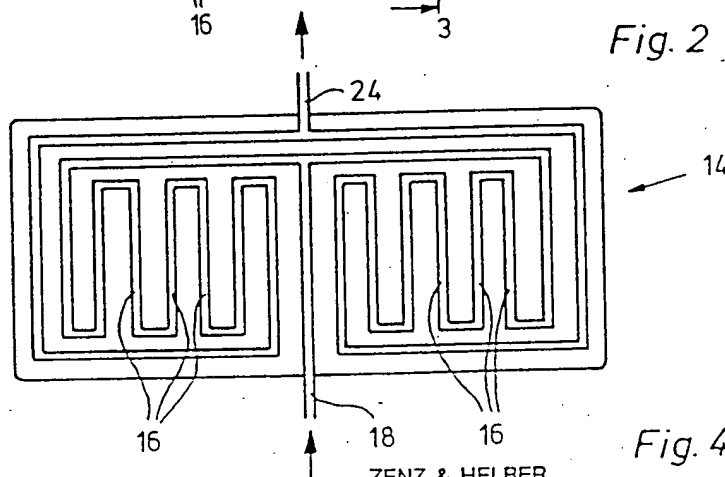


Fig. 4

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 PATENTANWÄLTE
 AM RUHRSTEIN 1
 D 4300 ESSEN 1

(12)

EUROPEAN PATENT APPLICATION

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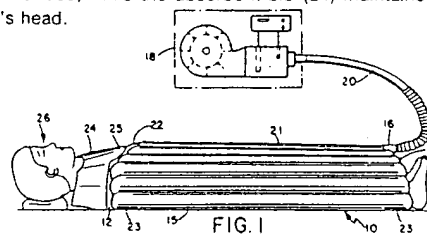
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(54) Thermal blanket.

(57) A thermal blanket (10) includes an inflatable covering with a head end (12), a foot end (14), two edges (15) and an undersurface. The covering is inflated through an inlet (16) at the foot end (14) by a thermally-controlled inflating medium. An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering. Exhaust port openings (23) are provided at the edges (15) of the covering to vent the inflating medium, which enhances circulation of the thermally-controlled medium through the cover. An uninflatable section (22) is provided at the head end (12), together with an absorbent bib (24) attached to the covering, adjacent the uninflatable section (22). When inflated, the thermal blanket (10) self-erects and provides a bath of thermally-controlled inflating medium to the interior of the erected structure. The enhanced circulation of the medium through the covers maintains a relatively high average temperature under the blanket (10) and a relatively uniform distribution of temperature in the inflating medium which is exhausted through the apertures into the structure's interior. When the structure covers a patient, the uninflatable section (22) provides a relatively unobstructed view of the patient's face, while the absorbent bib (24) maintains a relatively sanitary environment in the area beneath the patient's head.



EP 0 311 336 A1

THERMAL BLANKET

BACKGROUND OF THE INVENTION

This invention relates to thermal blankets used in a medical setting to deliver a bath of a thermally-controlled medium to a patient.

The thermal blanket prior art is best expressed in our prior U.S. Patent No. 4,572,188 entitled "AIRFLOW COVER FOR CONTROLLING BODY TEMPERATURE." In our prior patent, a self-erecting, inflatable airflow cover is inflated by the introduction into the cover of a thermally-controlled inflating medium, such as warmed air. When inflated, the cover self-erects about a patient, thereby creating an ambient environment about the patient, the thermal characteristics of which are determined by the temperature of the inflating medium. Holes on the underside of our prior art airflow cover exhaust the thermally-controlled, inflating medium from inside the cover to the interior of the erected structure. Our airflow cover is intended for the treatment of hypothermia, as might occur post-operatively.

Evaluation of our airflow cover by skilled practitioners has resulted in general approbation: the opinion is that the airflow cover efficiently and effectively accomplishes its purpose of giving a thermally-controlled bath. We have realized, however, that, while our prior art airflow cover achieves its objective, certain improvements to it are necessary in order to realize additional clinical objectives and to enjoy further advantages in its use.

20

SUMMARY OF THE INVENTION

We have improved the clinical usefulness of our self-erecting airflow cover by observing that controlling the contour of its inflatable portion at its head end to define a generally concave non-inflatable portion will permit a care giver to more easily observe a patient's head, face, neck and chest. Further, we have observed that limited venting of the thermally controlled inflating medium from the edges of the cover results in more efficient, more uniform heating within the cover. We have also observed that it is good clinical practice to keep the area of the care site in the vicinity of the patient's head and face as clean as possible.

These three observations have resulted in an improved thermal blanket in which a self-erecting inflatable covering has a head end, a foot end, two edges, and an undersurface. An inflating inlet adjacent said foot end admits a thermally-controlled inflating medium into the covering. An aperture array on the undersurface of the covering exhausts the thermally-controlled inflating medium from the covering into the structure created when the covering self-erects upon inflation. The improvements to this basic structural complement include an uninflatable section at the head end of the covering, exhaust port openings at the edges of the covering, an absorbent bib attached to the covering at the head end adjacent the uninflatable section, and structural features that make the covering simple and economical to produce.

With these improvements, the thermal blanket, when inflated and erected over a patient, delivers the thermally-controlled inflating medium into the interior of the structure covering the patient, thereby thermally bathing the patient. The first improvement permits full viewing of the head and face of the patient from almost any aspect around the thermal blanket. The exhaust port openings increase the rate of circulation of the inflating medium within the blanket, thereby increasing the temperature within the structure and making the temperature distribution more uniform. The absorbent bib soaks up and retains liquids which might otherwise spread over the care site in the area of a patient's head. Such liquids can include the patient's own perspiration, blood, vomit, saliva, or liquids which are administered to the patient. The absorbent bib also acts to some extent to seal the head end of the inflated structure.

From another aspect, the invention is a thermal blanket for covering and bathing a person in a thermally-controlled medium. The thermal blanket includes a flexible base sheet having a head end, a foot end, two edges, and a plurality of apertures opening between the first and second surface of the base sheet. An overlying material sheet is attached to the first surface of the base sheet by a plurality of discontinuous seams which form the material sheet into a plurality of substantially parallel, inflatable chambers. A continuous seam is provided between the material sheet and the base sheet at the head end to form a non-inflatable viewing recess at the head end. Exhaust port openings are provided through the material sheet to vent the medium from the chambers away from the base sheet. An absorbent bib is attached to the head end in the vicinity of the viewing recess.

Therefore the invention accomplishes the important objective of providing a self-erecting, inflatable thermal blanket that permits a relatively unobstructed view of a patient's head and face when in use.

Another objective is the efficient and uniform heating of the interior of the structure created when the blanket is inflated with a heat inflating medium.

5 A signal advantage of the invention is the provision of such a blanket with a means for maintaining the cleanliness of the care site in the vicinity of the patient's head and face.

The advantageous simplified structure of the thermal blanket make its production straightforward and economical.

10 These and other important objectives and advantages will become evident when the detailed description of the invention is read with reference to the below-summarized drawings, in which:

Figure 1 is a side elevation view of the thermal blanket in use, with associated thermal apparatus indicated schematically;

Figure 2 is an enlarged top plan view of the thermal blanket opened flat;

Figure 3 is an enlarged sectional view taken along 3-3 of Figure 2;

15 Figure 4 is a further enlarged sectional view taken along line 4-4 of Figure 3; and

Figure 5 is a partial underside view of the thermal blanket.

20 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

When used herein, the term "thermal blanket" is intended to be interchangeable with, but not necessarily limited by, the term "airflow cover" used in our U.S. Patent No. 4,572,188, which is incorporated herein in its entirety by reference. In this description, the term "thermal blanket" is meant to invoke a self-erecting, inflatable structure for delivering a thermally-controlled inflating medium to the interior of the structure created when the thermal blanket is inflated. The purpose of the thermal blanket is to efficiently administer a uniformly thermally-controlled bath of the inflating medium to a patient within the erected structure.

Our invention is illustrated as we intend for it to be used in Figure 1. In Figure 1, a self-erecting, inflatable thermal blanket 10 has a head end 12, a foot end 14 and two lateral edges, one indicated by 15. An inflation inlet cuff 16 is connected to a heater/blower assembly 18 which provides a stream of heated air through a connecting hose 20. When the heater/blower 18 is operated, the stream of heated air flows through the inflating hose 20 into the thermal blanket 10 through the inflation cuff 16. When the blanket is inflated, it erects itself into a Quonset hut-like structure with a quilted upper surface 21. As described below, a pattern of apertures on the undersurface of the blanket (not shown in Figure 1) delivers the inflating heated air into the interior space enclosed by the erected thermal blanket.

The contour of the inflatable portion of the thermal blanket 10 is varied at the head end 12 of the blanket to provide a non-inflated blanket recess 22 in the quilted upper surface 21, which remains smooth and flat when the blanket is inflated and erected. Circulation of the heated air is accelerated through the thermal blanket by exhaust port openings in the upper surface, adjacent the lateral edges of the blanket. Two exhaust port openings are indicated by reference numeral 23. Further, a bib 24 made of an absorbent material is attached to the head end 12 of the thermal blanket in the vicinity of the non-inflated recess 22. In fact, as shown in Figure 1, the bib 24 includes a semi-circular tab 25 that extends into the recess 22.

As illustrated in Figure 1, the thermal blanket of the invention is inflated, erects itself into a bathing structure, and bathes a patient 26 with the thermally-controlled air used to inflate the structure. While the patient is being thermally bathed, the uninflated recess 22 permits observation of the patient's head, face, neck, and chest from almost any location with respect to the thermal blanket 10. Thus, if the patient is placed on a gurney or a bed, the head of which is against a wall, a care giver such as a nurse, intern, resident, or doctor, can keep the patient's face under observation from the foot end 14 of the thermal blanket 10. Respiration can be detected by the rise and fall of the bib and uninflated area, which rest directly on the patient's chest. Moreover, the bib 24 will provide an absorbent sink for stray, unconfined liquids in the area of the patient's head or at the head end 12 of the thermal blanket 10.

Figure 2 is a plan view of the thermal blanket 10 opened flat to show details of its structure. Figure 2 illustrates the upper surface of the thermal blanket, that is the side that is visible in Figure 1. As seen, the upper surface consists of a parallel array of elongated tubes of which 30 and 32 are the lateralmost tubes, 34 is the center tube, and the tubes 38 are arrayed between one of the lateralmost tubes and the center tube. Each tube is separated from an adjacent tube by a discontinuous seam, one of which is indicated by 40. The seam 40 separates the tube 32 and its nearest adjacent neighbor 38. The discontinuous seam 40 is

interrupted by passageways 42 communicating between the tubes. An interrupted seam separates every tube from one adjacent neighboring tube. The seams permit the thermal blanket, when inflated, to assume a tubular structure on the upper surface, while the ports 42 permit full circulation of the inflating medium throughout the array of tubes. The foot-end seam 45 is continuous. The tubes are inflated through the center tube 34 which transitions to a port 36, through which the inflation cuff 16 is inserted. The edge seams 43 are discontinuous only at the exhaust port opening locations 23. A seal can be made between the inflation port 36 and the inflation cuff 16 by any conventional means, for example, an O-ring, or even tape. When the inflating medium is introduced into the center tube 34, it flows laterally from the center tube into all of the other tubes through the ports 42. Near the head end 12, a continuous seam 40 defines the forward end of all of the tubes, with the seam assuming a bell-curve shape. On the head end side of the seam 40, the thermal blanket 10 is uninflatable. The bell-shaped seam 40 thus defines the uninflatable area 22 at the head end of the thermal blanket 10, which is essentially coplanar with, or substantially parallel to, the underside of the blanket. As shown in Figure 1, by virtue of its structural integration with the rest of the thermal blanket 10, the non-inflated recess extends over the upper chest of the patient 26 when the blanket is inflated. However, since the recess 22 is uninflated, it provides a wide-angled viewing gap in the inflated contour of the upper surface 21. The gap is filled by continuation of the underside of the blanket. It is also noted that the pattern of inflatable tubes can be replaced by other suitable patterns of communicating, inflatable chambers. The tubes are preferred since they impart strength and shape to the erected bathing structure; other inflatable structures are contemplated, however.

The absorbent bib has an indent 43 cut into its outside edge, which permits the blanket to be drawn up to the chin of a patient and which provides absorbency laterally up the neck of the patient. The absorbent bib can consist of any absorbent material such as a single- or multi-ply tissue paper which is used to make paper towels.

Construction details of the thermal blanket 10 are illustrated in Figures 3 and 4. The thermal blanket 10 is assembled from a base sheet consisting of an underside layer 50 formed from flexible material capable of bonding to a layer 52 of heat-sealable plastic. For the layers 50 and 52, we have used a stratum of absorbent tissue paper prelaminated with a layer of heat-sealable plastic. Material of such construction is commercially available in production rolls and is used to make painters' drop cloths. The upper side of the thermal blanket consists of a sheet of plastic bonded to the plastic layer 52 by an interruptible heat-sealing process to form the interrupted seams, one of which is indicated by 54, and the inflatable tubes, one indicated by 55. As can be seen in Figure 3, the interruption of the seam 54 forms a passageway 56 between adjacent tubes 55 and 57.

The absorbent bib and tab are shown in Figure 3 as a single material layer 60/58. Alternatively, they may be formed from separate material sheets cut to the outlines illustrated in Figure 2. The absorbent material forming the bib and tab can be bonded to the upper plastic layer by heat process or by gluing.

The inventors also contemplate deletion of the bib and tab. In this instance, the thermal blanket would still have the viewing recess, which would be defined by the continuous seam at the head end, and which would be filled with the forward portion of the base sheet.

Circulation of heated air through the blanket is enhanced by the exhaust port openings 23, which open through the upper plastic sheet sheet, which is heat sealed to the base of the blanket. The openings 23 vent the heated inflating air out of the outermost tubes 30 and 32, away from the underside of the blanket. Because air can circulate to, and through, the blanket edges, the inflating air in the outermost tubes is hotter than if the openings were absent. This results in hotter air being delivered through the underside apertures toward the edge of the blanket. We have measured the temperature distribution within the thermal blanket for inflating air which is heated to a medium temperature range and for inflating air which is heated to a high temperature range. The results are provided in Table I for a blanket consisting of 13 tubes. Measurements of the temperature of air exhausted through underside apertures were made on the underside of each tube on one side of the blanket. The tubes are numbered 1-6, with 1 being the tube adjacent to the center tube, and tube 6 being the outermost tube adjacent on lateral edge of the blanket. Test apertures were made in the bottom of tube 6 only for the purposes of this test. As is evident, the distribution of temperature within the erected thermal blanket is more uniform when the exhaust port openings are provided. Further, provision of the exhaust ports also increases the average temperature within the erected structure of the blanket. Clearly, the provision of exhaust port openings at the lateral edges of the blanket delivers results which one would not expect when considering the operation of our thermal blanket with no exhaust port openings.

In our preferred embodiment, the exhaust port openings are slits in the edge seams of our blanket. These slits vary in length from 1-3/4 to 2 inches. Each edge seam is discontinuous approximately at each corner of the blanket so that inflating air is vented away from the underside of the erected blanket. This

keeps the relatively "colder" air at the blanket edges from mixing with the relatively "hotter" air exhausted into the structure through the underside apertures. The result is a "flatter" temperature profile of air within the blanket than without the vents, which raises the average temperature within the erected structure and makes the temperature distribution in the structure more uniform. Resultantly, the clinical effect of the blanket is enhanced. Heating is better controlled, and more uniform, with greater comfort to the patient.

TABLE I

TUBE NO.	MEDIUM TEMPERATURE RANGE		HIGH TEMPERATURE RANGE	
	WITHOUT EXHAUST PORTS	WITH 2" EXHAUST PORTS	WITHOUT EXHAUST PORTS	WITHOUT 2" EXHAUST PORTS
center (inlet) tube	113.3° F.	114.1° F.	121.3° F.	121.3° F.
Tube #1	109.9°	112.3°	117.3°	117.7°
Tube #2	105.3°	109.8°	113.4°	115.0°
Tube #3	103.2°	107.1°	111.0°	113.3°
Tube #4	99.9°	104.3°	101.4°	108.6°
Tube #5	97.2°	100.0°	95.7°	104.4°
Tube #6 (outermost)	85.2°	95.8°	89.6°	99.4°
Average temp. under cover	103.8°	106.7°	108.4°	112.5°

The thermal blanket of the invention is enabled to bathe a patient in the thermally-controlled inflating medium introduced into the upper side tubes by means of a plurality of apertures 62 shown in Figures 4 and 5. The apertures extend through the underside of the blanket, which includes the layers 50 and 52. The apertures 62 are made in the footprints of the tubes of the blanket upper side according to a pattern which has been determined to deliver a very uniform thermal bath. In this regard, no apertures are provided through the underside into the lateralmost tubes 30 and 32, or into the center tube 34. In addition, the apertures 62 are provided through the underside to the apertured tubes in a density which varies inversely with the proximity of the tube to the center tube 34. Thus, the hole density increases from the tube 38a through the tube 38d. Even with the exhaust port openings, the temperature of the inflating medium exhibits a drop from the center to the lateralmost tubes. The varying density of the apertures 62 tends to reduce this gradient further by forcing hotter air to the edges of the blanket. Thus, the thermal bath delivered to the patient is of a generally uniform temperature. The aperture density variation also equalizes the flow of inflating medium out of the apertures. As will be evident, the inflating pressure will be greatest at the center tube 34 and will tend to diminish toward the lateral edges of the thermal blanket. Therefore, fewer apertures are required for the tubes near the center tube 34 to deliver the same amount of air as the relatively greater number of apertures in the tubes at a greater distance from the center tube 34.

The apertures comprise openings which can be of any appropriate shape. For example, we have produced blankets with elongated apertures, approximately 1/7 inch in length.

Many modifications and variations of our invention will be evident to those skilled in the art. It is understood that such variations may deviate from specific teachings of this description without departing from the essence of the invention, which is expressed in the following claims.

Claims

1. A thermal blanket (10) for covering and bathing a person in a thermally-controlled inflating medium, comprising:
a flexible base sheet having a head end (12), a foot end (14), two edges (15), and a plurality of apertures (62);
an overlaying flexible material sheet attached to a first surface of said base sheet by a plurality of discontinuous seams (40) which form said overlaying material sheet into a plurality of communicating, inflatable chambers (30,32,34,38), said apertures (62) opening through said base sheet into said chambers; and

a continuous seam (40) between said overlaying material sheet and said base sheet at said head end which forms a non-inflatable viewing area (22) in said blanket at said head end, said non-inflatable viewing area (22) being substantially coplanar with, or parallel to, said base sheet.

2. The thermal blanket of claim 1, wherein said base sheet includes an undersheet of flexible fibrous material (50) and a sheet (52) of plastics material coextensive with and attached to said undersheet.

3. The thermal blanket of claim 1, wherein said base sheet includes a multi-layered structure in which the bottommost layer is a paper sheet (50) bonded to an upper sheet (52) of plastics material.

4. The thermal blanket of claim 2 or 3, wherein said discontinuous seams (40) are substantially elongate, heat-formed seals between said overlaying material sheet and sheet of plastics material.

5. The thermal blanket of claim 2, 3 or 4, wherein one of said discontinuous seams (40) includes a sequence of collinear, heat-formed seals extending from said foot end to said head end.

6. The thermal blanket of any one of the preceding claims, wherein said plurality of discontinuous seams form said overlaying material sheet into a plurality of mutually parallel, communicating tubular chambers (30,32,34,38).

7. The thermal blanket of any one of the preceding claims, including an exhaust port opening (23) through said material sheet adjacent one of said edges for venting an inflating medium from said chambers and away from said base sheet.

8. The thermal blanket of any one of the preceding claims, including a patterned array of apertures (62) opening through said base sheet into said chambers (30,32,34,38), said patterned array comprising a density pattern in which the density of said apertures increases toward at least one of said edges (15).

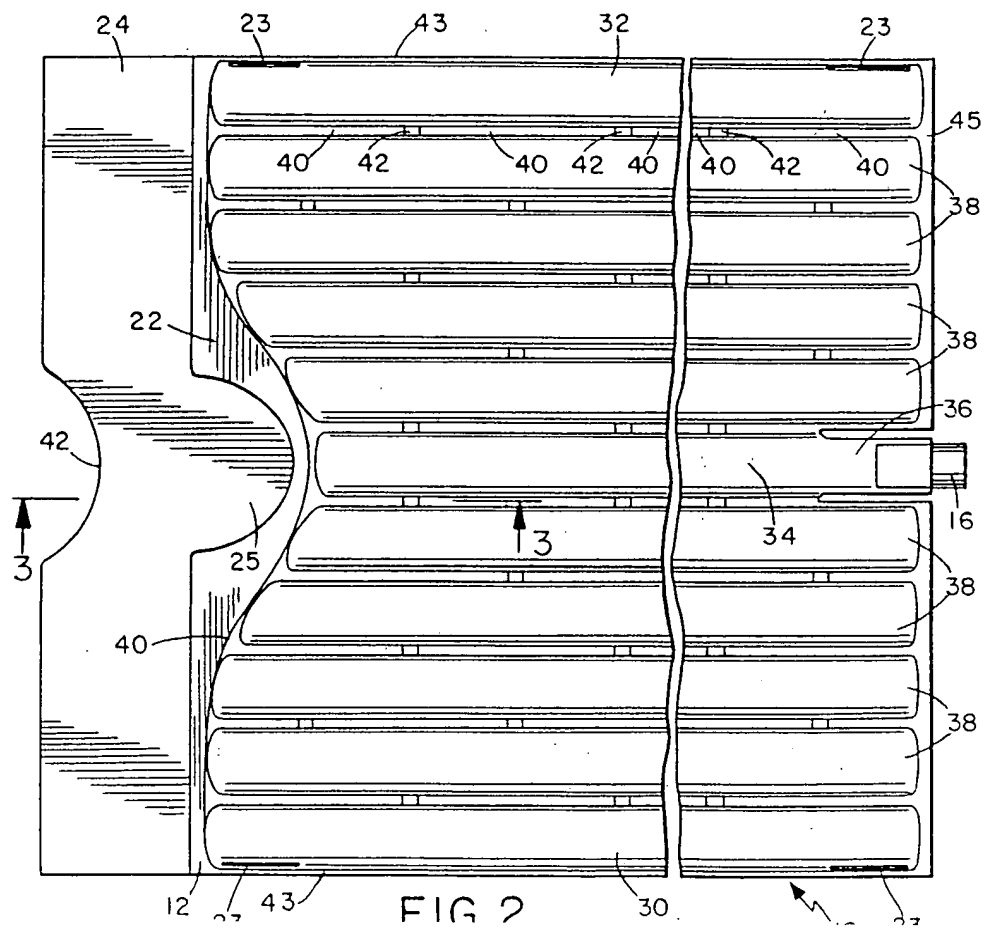
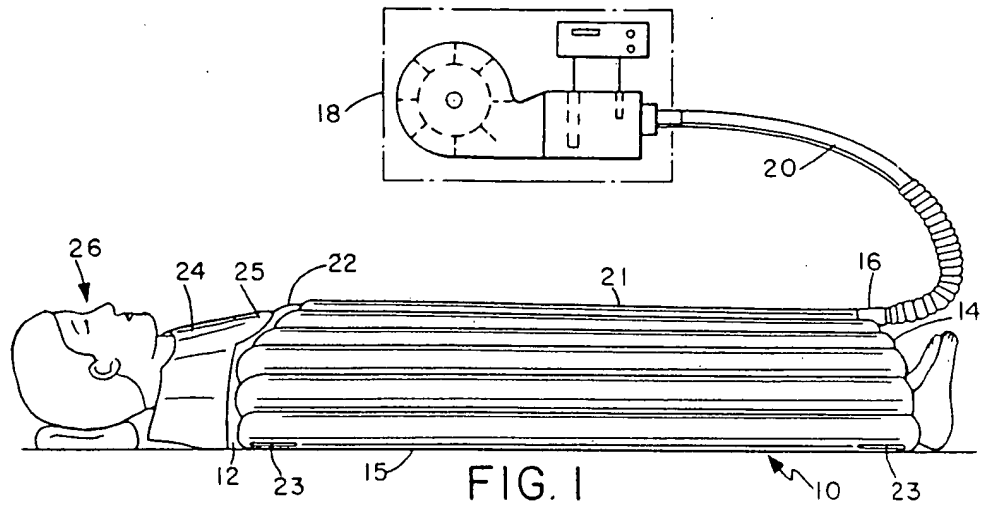
9. The thermal blanket of claim 8 when dependent on claim 6, wherein one of said tubular chambers (34) is centrally positioned in said parallel tubular chambers and said density increases from said centrally positioned chamber (34) toward at least one of said edges (15).

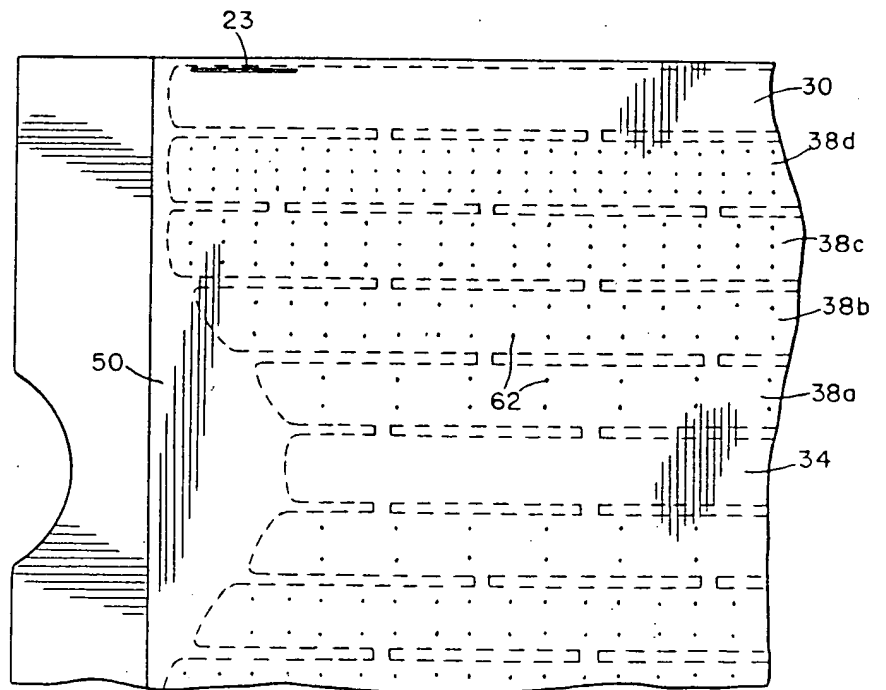
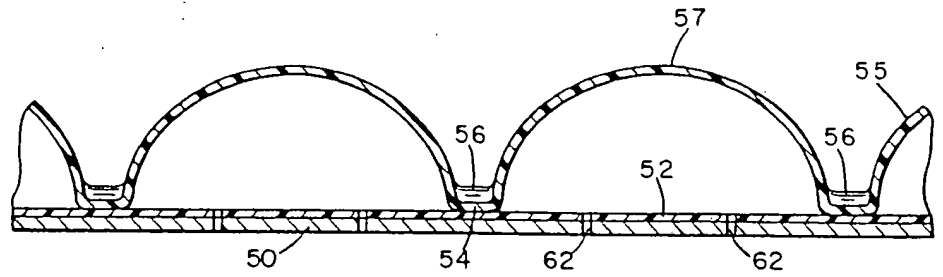
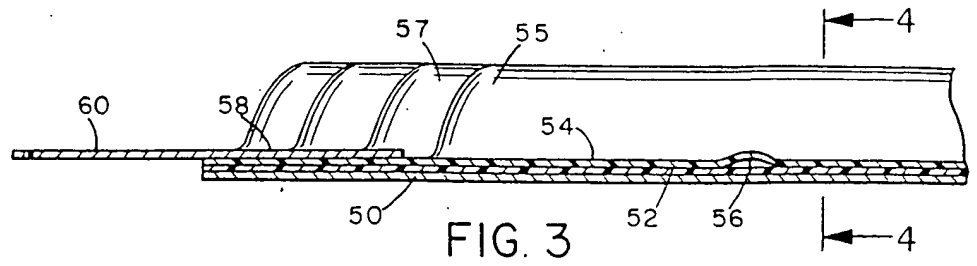
10. The thermal blanket of claim 9, wherein no apertures open through said base sheet into said centrally positioned tubular chamber (34).

11. The thermal blanket of claim 10, wherein no apertures open through said base sheet into a tubular chamber (30,32) adjacent one of said edges.

12. The thermal blanket of any one of the preceding claims, comprising an inflating inlet (16) adjacent said foot end (14) for admitting a thermally-controlled inflating medium.

13. The thermal blanket of any one of the preceding claims, including an absorbent bib (24) attached to the head end of said base sheet.







DOCUMENTS CONSIDERED TO BE RELEVANT			EP 88309191.0
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 4)
D, A	US - A - 4 572 188 (AUGUSTINE) * Abstract; column 2, line 64 - column 3, line 50; fig. 1, 2 * --	1, 6, 7, 12	A 61 F 7/00 A 61 F 7/08
A	DE - A1 - 3 308 553 (SMIDT) * Abstract; fig. 1, 2, 3 * --	1	
A	US - A - 3 714 947 (HARDY) * Abstract; fig. 1 * ----	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl. 4)
			A 61 F 7/00
The present search report has been drawn up for all claims			
Place of search VIENNA		Date of completion of the search 23-12-1988	Examiner TSILIDIS
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pocket; also: a mine having a shaft (a ~ worth millions) 2 a ~ (a ~) *terprise* (put the full resources of his studio behind the picture ~ and achieved a box-office ~) -AI Hinc) *B*: an extremely large amount (a ~ of Socialist sympathy ~ *Time*) *C*: something extremely rich, lush, or rewarding (the ~ farms of the middle west ~ Lewis Mumford (*a era*) ~) *bo-na-part's* *1* *bo-na-part's* *2* *bo-na-part's* *3* *bo-na-part's* *4* *bo-na-part's* *5* *bo-na-part's* *6* *bo-na-part's* *7* *bo-na-part's* *8* *bo-na-part's* *9* *bo-na-part's* *10* *bo-na-part's* *11* *bo-na-part's* *12* *bo-na-part's* *13* *bo-na-part's* *14* *bo-na-part's* *15* *bo-na-part's* *16* *bo-na-part's* *17* *bo-na-part's* *18* *bo-na-part's* *19* *bo-na-part's* *20* *bo-na-part's* *21* *bo-na-part's* *22* *bo-na-part's* *23* *bo-na-part's* *24* *bo-na-part's* *25* *bo-na-part's* *26* *bo-na-part's* *27* *bo-na-part's* *28* *bo-na-part's* *29* *bo-na-part's* *30* *bo-na-part's* *31* *bo-na-part's* *32* *bo-na-part's* *33* *bo-na-part's* *34* *bo-na-part's* *35* *bo-na-part's* *36* *bo-na-part's* *37* *bo-na-part's* *38* *bo-na-part's* *39* *bo-na-part's* *40* *bo-na-part's* *41* *bo-na-part's* *42* *bo-na-part's* *43* *bo-na-part's* *44* *bo-na-part's* *45* *bo-na-part's* *46* *bo-na-part's* *47* *bo-na-part's* *48* *bo-na-part's* *49* *bo-na-part's* *50* *bo-na-part's* *51* *bo-na-part's* *52* *bo-na-part's* *53* *bo-na-part's* *54* *bo-na-part's* *55* *bo-na-part's* *56* *bo-na-part's* *57* *bo-na-part's* *58* *bo-na-part's* *59* *bo-na-part's* *60* *bo-na-part's* *61* *bo-na-part's* *62* *bo-na-part's* *63* *bo-na-part's* *64* *bo-na-part's* *65* *bo-na-part's* *66* *bo-na-part's* *67* *bo-na-part's* *68* *bo-na-part's* *69* *bo-na-part's* *70* *bo-na-part's* *71* *bo-na-part's* *72* *bo-na-part's* *73* *bo-na-part's* *74* *bo-na-part's* *75* *bo-na-part's* *76* *bo-na-part's* *77* *bo-na-part's* *78* *bo-na-part's* *79* *bo-na-part's* *80* *bo-na-part's* *81* *bo-na-part's* *82* *bo-na-part's* *83* *bo-na-part's* *84* *bo-na-part's* *85* *bo-na-part's* *86* *bo-na-part's* *87* *bo-na-part's* *88* *bo-na-part's* *89* *bo-na-part's* *90* *bo-na-part's* *91* *bo-na-part's* *92* *bo-na-part's* *93* *bo-na-part's* *94* *bo-na-part's* *95* *bo-na-part's* *96* *bo-na-part's* *97* *bo-na-part's* *98* *bo-na-part's* *99* *bo-na-part's* *100* *bo-na-part's* *101* *bo-na-part's* *102* *bo-na-part's* *103* *bo-na-part's* *104* *bo-na-part's* *105* *bo-na-part's* *106* *bo-na-part's* *107* *bo-na-part's* *108* *bo-na-part's* *109* *bo-na-part's* *110* *bo-na-part's* *111* *bo-na-part's* *112* *bo-na-part's* *113* *bo-na-part's* *114* *bo-na-part's* *115* *bo-na-part's* *116* *bo-na-part's* *117* *bo-na-part's* *118* *bo-na-part's* *119* *bo-na-part's* *120* *bo-na-part's* *121* *bo-na-part's* *122* *bo-na-part's* *123* *bo-na-part's* *124* *bo-na-part's* *125* *bo-na-part's* *126* *bo-na-part's* *127* *bo-na-part's* *128* *bo-na-part's* *129* *bo-na-part's* *130* *bo-na-part's* *131* *bo-na-part's* *132* *bo-na-part's* *133* *bo-na-part's* *134* *bo-na-part's* *135* *bo-na-part's* *136* *bo-na-part's* *137* *bo-na-part's* *138* *bo-na-part's* *139* *bo-na-part's* *140* *bo-na-part's* *141* *bo-na-part's* *142* *bo-na-part's* *143* *bo-na-part's* *144* *bo-na-part's* *145* *bo-na-part's* *146* *bo-na-part's* *147* *bo-na-part's* *148* *bo-na-part's* *149* *bo-na-part's* *150* *bo-na-part's* *151* *bo-na-part's* *152* *bo-na-part's* *153* *bo-na-part's* *154* *bo-na-part's* *155* *bo-na-part's* *156* *bo-na-part's* *157* *bo-na-part's* *158* *bo-na-part's* *159* *bo-na-part's* *160* *bo-na-part's* *161* *bo-na-part's* *162* *bo-na-part's* *163* *bo-na-part's* *164* *bo-na-part's* *165* *bo-na-part's* *166* *bo-na-part's* *167* *bo-na-part's* *168* *bo-na-part's* *169* *bo-na-part's* *170* *bo-na-part's* *171* *bo-na-part's* *172* *bo-na-part's* *173* *bo-na-part's* *174* *bo-na-part's* *175* *bo-na-part's* *176* *bo-na-part's* *177* *bo-na-part's* *178* *bo-na-part's* *179* *bo-na-part's* *180* *bo-na-part's* *181* *bo-na-part's* *182* *bo-na-part's* *183* *bo-na-part's* *184* *bo-na-part's* *185* *bo-na-part's* *186* *bo-na-part's* *187* *bo-na-part's* *188* *bo-na-part's* *189* *bo-na-part's* *190* *bo-na-part's* *191* *bo-na-part's* *192* *bo-na-part's* *193* *bo-na-part's* *194* *bo-na-part's* *195* *bo-na-part's* *196* *bo-na-part's* *197* *bo-na-part's* *198* *bo-na-part's* *199* *bo-na-part's* *200* *bo-na-part's* *201* *bo-na-part's* *202* *bo-na-part's* *203* *bo-na-part's* *204* *bo-na-part's* *205* *bo-na-part's* *206* *bo-na-part's* *207* *bo-na-part's* *208* *bo-na-part's* *209* *bo-na-part's* *210* *bo-na-part's* *211* *bo-na-part's* *212* *bo-na-part's* *213* *bo-na-part's* *214* *bo-na-part's* *215* <

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Table 3. Bond angles for three triatomic molecules

Molecule	Name	Angle	Value
H ₂ O	Water	H—O—H	105°
SO ₂	Sulfur dioxide	O—S—O	119°
CO ₂	Carbon dioxide	O—C—O	180°

Theoretical calculation. Quantum mechanics can, in principle, be used to calculate bond lengths and angles accurately by solving the appropriate quantum-mechanical equations, although such calculations for large molecules are extremely difficult and require a great deal of computer time. A number of simple theoretical concepts have been developed that have some approximate correlation with experimentally determined bond angles and distances. One is called the electrostatic or valence-shell electron-pair repulsion model. It treats a chemical bond as a shared pair of electrons which repels other pairs associated with the other atoms. An alternative model, valence-bond theory, treats a chemical bond as an overlap of electronic orbitals centered on the bonded atoms. A third model, hybrid orbitals centered on the same atoms have a characteristic geometry. *SEE CHEMICAL STRUCTURES; QUANTUM CHEMISTRY; VALENCE.*

Bruce A. Garetz

Bibliography. J. H. Callomon et al., *Structure Data of Free Polyatomic Molecules*, vol. 7 of Landolt-Bornstein, Group II, *Atomic and Molecular Physics*, 1976; M. D. Harmony et al., *J. Phys. Chem. Ref. Data*, 8:619-721, 1979; K. P. Huber and G. Herzberg, *Constants of Diatomic Molecules*, 1979; I. Levine, *Physical Chemistry*, 3d ed., 1988; J. N. Murrell et al., *The Chemical Bond*, 2d ed., 1985; L. Pauling, *The Nature of the Chemical Bond*, 3d ed., 1960.

Bonding

with a method of holding the parts of an object together with epoxy or a glue. Composite materials such as fiber-reinforced plastics require strong interfacial bonding between the reinforcement and the matrix. In the case of atomic or optical contact bonding, interatomic forces hold the parts together. In optical contact bonding, surface flatness and cleanliness between the mating parts determine the bonding strength, and the number of valence electrons provide the necessary forces. The determines the bonding strength in the atoms of a material atoms which constitutes a molecule. In these cases the term chemical bonding is used. *SEE ADHESIVE; CHEMICAL BONDING; COMPOSITE MATERIAL.*

Wire bonding is an interconnection method of an integrated circuit chip and the electrical leads of the package housing the chip. The two common methods of wire bonding are thermocompression and ultrasonic bonding. In these, a fine aluminum or gold wire is bonded at one end to the metal pad of the integrated circuit chip, and at the other to the electrical lead of the package. There are three types of thermocompression bonds: wedge, stitch, and ball. In thermocompression bonding, a molecular metallurgical bond is formed at the two metal junctions—bond wire and IC metal

pad, and bond wire and package lead metal—by applying heat and pressure without melting. In ultrasonic bonding, the molecular metallurgical bond is achieved through a combination of ultrasonic energy and pressure. The bonding operation is done under pressure to break the few surface layers of the material and form the bond between the contamination-free surfaces. Thermocompression bonding has higher throughput and speed than ultrasonic bonding. The bonding wire is usually aluminum, which does not introduce any intermetallic problems. *SEE CIRCUIT (ELECTRONICS); INTEGRATED CIRCUITS.*

Lakshmi Munukutla

Bone

The hard connective tissue that, along with cartilage, forms the skeleton of vertebrates. *SEE CONNECTIVE TISSUE.* For a detailed discussion of the histology of bone *SEE SKELETAL SYSTEM.*

Bone is a complex substance with remarkable abilities of structural adaption. One of the functions of bone is structural. It forms the skeleton, which provides mechanical support and protection for the organism. *SEE BONES AND THE SKELETAL SYSTEM.* Throughout life the skeleton is continually changing to adapt its form and structure for this function. *SEE MUSCULAR SYSTEM.*

The other major function of bone tissue is metabolic. It maintains a mineral homeostasis in the organism by regulating the concentrations of key blood electrolytes, including calcium. The parathyroid glands are essential for this regulation. Calcium is necessary for nerve conduction, muscle contraction, clot formation, cell secretion, and other metabolic activities. *SEE CALCIUM METABOLISM; PARATHYROID GLAND.*

Composition and microstructure. Bone tissue, the material of which whole bones are made, consists of cells in an extracellular matrix. The cells are numerous and biologically very important, but since they occupy such a small volume, bone tissue is, effectively, the extracellular matrix. This matrix has two principal ingredients, collagen and an inorganic mineral phase called apatite or hydroxyapatite consisting primarily of calcium phosphate crystals. The apatite is arranged in a regular pattern in the collagen fibers. When the mineral is removed from bone tissue, the demineralized matrix is mostly collagen and loses its stiffness. *SEE APATITE; COLLAGEN.*

At the macroscopic level there are two major forms of bone tissue, compact (cortical) and spongy (cancellous/trabecular). Compact bone, a dense material with a specific gravity of about 2, forms the outer shell of all bones. Spongy bone exists at the ends of long bones, within the vault of the skull, and generally within the confines of a cortical bone shell. The short ends of bone in spongy bone are trabeculae.

At the microstructural level, both spongy bone and compact bone have a lamellar organization. The trabeculae of spongy bone generally are composed of a collection of more or less parallel lamellae. In compact bone the lamellae may be arranged either in parallel fashion or concentrically in quasicylindrically shaped structures called osteons (Haversian systems). The circumferentially arranged parallel lamellae are found near the outer and inner surfaces of the compact bone. These two different types of normal well-organized compact bone tissue are called lamellar and osteonal. The greatest volume of the compact bone is

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